UNIVERSITY OF LIVERPOOL

# Designing and Programming an Intelligent Implantable Wireless Hydrocephalus Shunting System

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by

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# Abstract

Hydrocephalus is a neurological disorder whereby the cerebro-spinal fluid surrounding the brain is improperly drained, causing severe pain and swelling of the head. Existing treatments rely on passive implantable shunts with differential pressure valves; these have many limitations, and life-threatening complications often arise. In addition, the inability of such devices to autonomously and spontaneously adapt to the needs of the patients results in frequent hospital visits and shunt revisions.

This work proposes replacing the passive valve with a mechatronic valve and an intelligent microcontroller that wirelessly communicates with a hand-held device that would have a Graphical User Interface (GUI) and an RF interface to communicate with the patient and the implantable shunt respectively. This would deliver a personalised management and treatment. This system would also enable a physician to monitor and modify the treatment parameters wirelessly, thus reducing, if not eliminating, the need for shunt revision operations.

To manage the shunt, four methods were investigated, simulated and compared. As a result a method was selected based on performance.

A bidirectional communication protocol has been proposed and developed to wirelessly manage such a mechatronic shunting system. Such a protocol was proposed to manage all the proposed shunt functions. The management shunting protocol was implemented and tested to demonstrate practicality, reliability and flexibility of the proposed system. In addition, a power consumption algorithm was proposed and developed to improve the performance of the proposed shunt by reducing the power needed for the implanted components. With such a protocol, the proposed shunting system gives hydrocephalus patients the freedom to go anywhere they wish while receiving medical services and healthcare in a timely fashion.

Various parameters that characterise the shunt behaviour in malfunction situation were extracted and investigated to help in detecting and identifying shunt faults. A Complementary fuzzy-logic-based fault diagnosis system was developed to diagnose the faults of an implantable shunting system. By using such a method, various current shunt malfunctions can be detected early and their types can be also predicted. In order to evaluate system performance, the accuracy of the fuzzy logic classifier was tested. Using the developed fault diagnosis system, six general

faults were successfully diagnosed in real time. With these characteristics, the system could be efficiently used for fault diagnosis in hydrocephalus shunting.

This work presents the design and implementation of an expert system based on real-time patient feedback that aims to provide a suitable decision making system for hydrocephalus management and shunt diagnosis. Such a decision making system would help in personalising the management as well as detecting and identifying any shunt malfunctions without the need to contact or visit the hospital. In this work, the development of patient feedback expert system is presented. The outcome of such a system would be satisfying patient's needs regarding his/her shunt.

A self learning method based on learning from hydrocephalus database was investigated and simulated. In this method, trends of various intracranial pressure (ICP) parameters which are derived from the shunting database have been used to help the system to detect faults in its early stages and to monitor the effect of such faults on shunt performance step by step. In addition, the system can estimate the times required for the ICP to be abnormal and for the valve to reach full blockage case. Furthermore, an auto valve schedule updating method is proposed and used to temporarily deal with any early fault detection until the patient is checked by his/her physician.

A design of a multi-agent system for self-diagnosis of the hydrocephalus shunting system was described. Six types of agents have been proposed to detect any faults in a hierarchical way. This work proposes one of the most promising methods for the self-diagnosis and monitoring of a hydrocephalus shunting system based on a novel multi-agent approach.

The difficulty of evaluation and testing of the proposed shunting system and proposed method in a clinical environment or in vivo motivated the researcher to simulate such system. The proposed prototype was used to test and evaluate the management and treatment software as well as the diagnosis methods. The evaluation results validate the proposed design, the bidirectional management protocol, self diagnosis method and self learning and auto valve schedule updating methods. To conclude, an intelligent shunting system is seen as the future in hydrocephalus treatment, potentially reducing significantly hospitalisation periods and shunt revisions.

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# Abbreviations

| | |
|---|---|
| ABP | Arterial Blood Pressure |
| CSF | Cerebro Spinal Fluid |
| CT | Computerised Tomography |
| FoM | Figure of Merit |
| ICP | Intra Cranial Pressure |
| RF | Radio Frequency |
| AEGs | Aterial Electro Grams |
| AERP | Aterial Effective Refractory Period |
| PC | Personal Computer |
| FM | Frequency Modulated |
| AC | Alternating Current |
| MICS | Medical Implantable Communication Standards |
| BMOO | Bovine Mobile Observation Operation |
| DICOM | Digital Imaging and Communications in Medicine |
| PDAs | Personal Digital Assistants |
| FCC | Federal Communications Commission |
| BOM | Bill Of Material |
| BAN | Body Area Network |
| ADK | Application Development Kit |
| BSM | Base Station Module |
| AIM | Application Implant Module |
| LPM3 | Low Power Mode3 |
| MAB | Memory Address Bus |
| MDB | Memory Data Bus |

| | |
|---|---|
| CPU | Central Processing Unit |
| RTC | Real Time Clock |
| ETV | Endoscopic Third Ventriculostomy |
| ICE | Internal Combustion Engines |
| KSPS | Kilo Samples Per Second |
| BDI | Belief Desire Intention |
| PDT | Prometheus Design Tool |
| AUML | Agent Unified Modeling Language |

*This thesis is dedicated to my wife Lina who has been a great source of motivation and inspiration, and supported me all the way since the beginning of my studies. Also, this thesis is dedicated to my daughters Hala, Sara and Mira who offered me unconditional love and support throughout the course of this thesis.*

# Chapter 1

# Introduction

Telecommunication technologies are being used to improve healthcare in unprecedented. Recently, personalisation of healthcare has had the potential to enable tailored medical and surgical treatments with significantly improved outcomes compared to conventional treatments. Solutions, such as body-worn sensors for clinical and healthcare monitoring, improve quality of life by offering patients greater independence. Such solutions can go beyond monitoring to active intervention and treatment based on sensory measurement and patient feedback, effectively taking healthcare out of the hospital environment. Such personalised solutions play an increasingly important role in delivering high quality and cost-effective healthcare. Now is an appropriate time to use such technology in the treatment of physiological disorders such as hydrocephalus. This thesis is concerned with the possibilities of using such technology in the area of designing and programming an intelligent implantable hydrocephalus shunting system that seeks to autonomously treat the patients while also monitoring and diagnosing the health of the implanted system itself.

## 1.1 Problem Definition

Shunt systems are not perfect devices and complications often arise. Complications may include mechanical failure, infections, obstructions, and the need to lengthen or replace the catheter. Generally, shunt systems require monitoring and regular medical follow up. At present, follow-up of shunted patients varies among neurosurgical centres. In some, the patient is seen annually and more frequently if his/her management proves more difficult. Others adopt a more open form of follow-up where patients are only seen if they develop problems . The methods used to date have been based on clinical presentation of shunt malfunctions, clinical data, imaging techniques and evaluation of valve function in mechanical terms. All these systems fail to pick up the daily variations in the patient's condition, the build-up of symptoms prior to deteriorations and do not reflect the differences needed in monitoring individual patients.

Symptoms of various shunt complications (seizures, a significant change in intellect, school performance, or personality) can be very similar and difficult to spot thus complicating the diagnosing process. On the other hand, the possible presentations of acute shunt malfunction in early stages are innumerable for many reasons such as the lack of non invasive intracranial pressure (ICP) and flow monitoring. In addition, shunt malfunctions might be present even if they have not shown on a CT or MRI scans and also the number of these should be minimised due to the use of radiation and are therefore not desirable for regular use. The early detection and recognition of shunt malfunctions to prevent or minimise complications and maximise shunt functioning has long been accepted as a desirable goal in the treatment of hydrocephalus. Despite ICP monitoring currently being an invasive procedure, patients with hydrocephalus may need repeated episodes of monitoring months or years apart. This involves hospitalisation, patient suffering, and might endanger the patient's life.

The patient needs to visit a hospital or meet a consultant for diagnosing every time he/she complains from symptoms. And since these symptoms (e.g. headache, vomiting, fever) are similar to the symptoms of other medical problems, the hydrocephalus patient would worry every time he/she has such symptoms. In this case, the patient will only be assured if he/she contacted a physician. This involves waste of patient and physician time and cost if the cause of the symptoms was not due to shunt malfunction.

Biomedical implants require a clean and medically safe source of energy to perform their operations. Limited battery life causes the impracticality, health risks and expense of operating on patients for the mere purpose of replacing the battery. Up to this moment, the implanted battery needs to be replaced when it loses its capacity. Thus minimising power consumption is essential for any implantable device. In addition, memory size limitation is another obstacle that faces biomedical implants [53].

To address the the above problems, an intelligent wireless shunting system needs to be designed. By having such system, the hospitalisation periods and patient suffering and inconvenience are reduced, the quality of treatment is improved and better understanding of intracranial hydrodynamics is established thanks to the valuable resource of ICP data collected by an implanted sensor.

This research proposes an intelligent implantable wireless hydrocephalus shunting system. It aims to replace the passive shunt with an intelligent microcontroller that wirelessly communicates with a hand-held device operated by the patient, or on the patient's behalf by a clinician or guardian. This device would have a graphical user interface, microcontroller and an RF interface to communicate with the user and the implantable wireless electronic shunt. The implantable wireless shunting system would consist of electronic valve, intracranial pressure sensor, flowmeter, microcontroller and RF transceiver. Also an embedded implantable shunting software would autonomously regulate the electronic valve.

## 1.2 Objectives

This research aims to design and program an intelligent implantable wireless hydrocephalus shunting system that would upgrade the current mechanical shunt systems allowing it to:

- Update valve schedule to compensate for patient needs *i.e.* personalise treatment, patient satisfaction,
- Personalise the treatment of hydrocephalus through involving the patient's real-time feedback and ICP readings,
- Self diagnose its implanted components to early detect any malfunction and reduce shunt revision,
- Monitor in Real time the ICP and shunt components noninvasively.

## 1.3 Contribution

The original contribution of this research can be summarised as follows.

1. One aspect of this work is the idea of wirelessly reprogramming the implanted shunting system by modifying the implanted valve and ICP sensor schedules. A wireless management shunt protocol would enable the physician to control, manage and treat the hydrocephalus and utilise real-time ICP readings. In addition, it would be an infrastructure for a self diagnosis system that is

needed for early detection of shunt faults based on various sensory inputs such as malfunction parameters and instantaneous patient feedback. Thus enabling real-time reconfiguration of various shunt parameters.

2. Proposing and implementing an algorithm for power consumption to manage and reduce the power needed for implanted shunt components. The outcome of such an algorithm would reduce the power needed by more than 90%.

3. Proposing a method for utilising the ICP data and valve flow measurement that would extract useful faults detection parameters for self diagnosis shunting system.

4. Proposing a technique based on fuzzy logic that would diagnose the shunt based on fault detection parameters.

5. Proposing a novel technique based on expert system for patient feedback analysis and management that would be used to improve hydrocephalus patient treatment, reduce the patient suffering and treatment cost.

6. Proposing a novel technique based on self learning method that would use the hydrocephalus database for detecting patterns and trends of fault detection parameters. This would help in early detection and prediction of any shunt malfunctions or rising/drift of the ICP due to any reasons, as well as updating the valve schedule to compensate for such malfunctions.

## 1.4 List of Publications

The following publications have arisen as a direct result of the author's research.

1. Two journal papers are in preparation to be submitted soon to Hydrocephalus and MBEC journals.

2. A. Alkharabsheh, L. Momani, N. Al-Zubi and W. Al-Nuaimy, Fuzzy Logic Based Fault Detection and Diagnosis of a Mechatronic Hydrocephalus Shunting System, the *1st International Conference on Applied Bionics and Biomechanics (ICABB-2010)*, Oct. 14-16, 2010, Venice, Italy.

3. A. Alkharabsheh, L. Momani, N. Al-Zubi and W. Al-Nuaimy, An Expert System for Hydrocephalus Patient Feedback, *32nd Annual International IEEE EMBC Conference*, Aug 31 - Sep 4, 2010, Buenos Aires, Argentina.

4. A. Alkharabsheh, L. Momani, N. Al-Zubi and W. Al-Nuaimy, A Multi-Agent Approach for Self-Diagnosing of Hydrocephalus Shunting System, *The Third conference of Developments in E-Systems Engineering (DeSE)*, 6th - 8th Sep 2010, London, UK.

5. A. Alkharabsheh, L. Momani, N. Al-Zubi, and W. Al-Nuaimy, A Real-Time Self diagnosis Method for a Hydrocephalus Shunting System, in *4th Annual Symposium of the Benelux Chapter of the IEEE Eng Med Biol Soc. (EMBS)*, The Netherlands, Nov 2009.

6. L. Momani, A. Alkharabsheh, and W. Al-Nuaimy, Intelligent and Personalised Hydrocephalus Treatment and Management, (book chapter) in *Biomedical Engineering*, Carlos Alexandre Barros de Mello (Ed.), 2009, ISBN: 978-953-307-013-1, INTECH.

7. A. Alkharabsheh, L. Momani, N. Al-Zubi, and W. Al-Nuaimy, A Bidirectional Wireless Management Protocol for Mechatronic Shunting System, in *4th International Conference on Broadband Communication, Information Technology and Biomedical Applications*, Wroclaw, Jul 2009.

8. A. Alkharabsheh, L. Momani, N. Al-Zubi and W. Al-Nuaimy, An Intelligent Implantable Wireless Shunting System for Hydrocephalus Patients, in *Proceedings of 13th International Conference on Biomedical Engineering*, Suntec, Singapore, pp. 210-215, Dec 2008.

The following publications are the result of the research group work, where the author appears as a co-author,

1. Nayel Al-Zubi, Abdulrahman Al-kharabsheh, Lina Momani and Waleed Al-Nuaimy. Intelligent Shunt Agent for Gradual Shunt removal, *32nd Annual International IEEE EMBC Conference*, Aug 31 - Sep 4, 2010, Buenos Aires, Argentina.

2. L. Momani, A. Alkharabsheh, N. Al-Zubi, and W. Al-Nuaimy, Reduction of Mechatronic Shunt Dependence for Hydrocephalus Patients, in *4th Annual Symposium of the Benelux Chapter of the IEEE Eng Med Biol Soc. (EMBS)*, the Netherlands, Nov 2009.

3. L. Momani, A. Alkharabsheh, N. Al-Zubi, and W. Al-Nuaimy, Instantiating a Mechatronic Valve Schedule for a Hydrocephalus Shunt, in *Conf Proc IEEE Eng Med Biol Soc.*, Minnesota, USA, pp. 749-752, Sep 2009.

4. N. Al-Zubi, L. Momani, A. Alkharabsheh, and W. Al-Nuaimy, Multivariate Analysis of Intracranial Pressure (ICP) Signal Using Principal Component Analysis, in *Proceedings of the IEEE Eng Med Biol Soc.*, Minnesota, USA, pp. 4670-4673, Sep 2009.

5. N. Al-Zubi, A. Alkharabsheh, L. Momani and W. Al-Nuaimy, Distributed Multi-agent Approach for Hydrocephalus treatment and management Using Electronic Shunting, in *HEALTHINF*, Portugal, pp. 503-507, Jan 2009.

6. L. Momani, A. Alkharabsheh and W. Al-Nuaimy, Design of an Intelligent and Personalised Shunting System for Hydrocephalus, in *Proceedings of IEEE Eng Med Biol Soc.*, Vancouver, Canada, pp. 779-782, Aug 2008.

7. L. Momani, W. Al-Nuaimy, M. Al-Jumaily, C. Mallucci, A. Al-Kharabsheh and Y. Huang, Simulation of a Smart Hydrocephalus Shunting System, in *35th Annual Meeting of the International Society for Pediatric Neurosurgery*, Liverpool, UK, Sep 2007.

8. L. Momani, W. Al-Nuaimy, M. Al-Jumaily, C. Mallucci, A. Al-Kharabsheh and Y. Huang, Simulation of a "Blind" Mechatronic Valve for a Hydrocephalus Shunt, in *Hydrocephalus Workshop* - Rhodes, Greece, May 2007.

## 1.5 Thesis Structure

This thesis consists of eleven chapters. In Chapter 2, the proposed intelligent shunting system is introduced and the shunt component selection process is detailed. Chapter 3 presents the system simulation and design optimisation. In Chapter 4, the bidirectional wireless shunting management protocol is outlined. In Chapter 5, self diagnosis and blockage detection are investigated where diagnosis parameters are derived and various shunt faults are simulated. In addition, a real-time self diagnosis method is proposed. A fuzzy logic based fault detection and diagnosis technique is proposed in Chapter 6. Chapter 7 presents analysis of hydrocephalus patient feedback in real-time based on an expert system. In Chapter 8, a self-learning database method for diagnosis of hydrocephalus shunting system is illustrated. A multi-agent self-diagnosis system approach is introduced in Chapter 9. A prototype of hydrocephalus treatment and diagnosis shunting system is illustrated in Chapter 10 for evaluation and testing of the proposed system. This is followed by discussion of the main conclusions and outlining future prospects in the final chapter.

# Chapter 2

# An Intelligent Implantable Wireless Shunting System

## 2.1 Introduction

Hydrocephalus is a neurological disorder whereby the cerebro-spinal fluid (CSF) surrounding the brain builds up, causing severe pain and swelling of the head [11]. This is particularly prevalent in infants, and is becoming more common.

Shunts were used for decades to treat hydrocephalus patients, where mechanical valves were the popular type for draining the CSF. The problem is these valves have serious drawbacks e.g. overflow, low long-term accuracy, drift, low durability. In addition, almost the same treatment is used for all hydrocephalus patients without taking into consideration patient's personal factors (such as medical history, sleep patterns and lifestyle) and it cannot handle real-time patient satisfaction and emergency situations. This makes the conventional mechanical shunt satisfying less of 50% of its patients. Nowadays, and after long history with such valves, it is found that, it is the proper time to use electronic valves.

In this chapter, a wireless mechatronic shunting system has been illustrated. The system requirement, suitable components selection, power calculation and initial system analysis and design have been illustrated in detail. The proposed shunting system mainly consists of two subsystems. The first subsystem is an implantable shunting system which would regulate the valve of the shunt according to the embedded implantable valve schedule and any updating that would be received from the external subsystem. The second subsystem is an external shunting system that would be used to access the implantable shunting system and to access the central hospital database. Current treatment is explored, where shunt components, types, related patents and drawbacks are viewed. Shunts in the literature and recent advances are summerised, followed by a discussion of the main conclusions.

## 2.2 Overview of Hydrocephalus

Hydrocephalus is neurological disorder caused by blockage or reabsorption difficulty that upsets the natural balance of production and absorption of cerebrospinal fluid in the brain, resulting in a build-up of the fluid in the ventricles of the brain, which leads to an increase in the intracranial pressure (ICP). To understand this disorder, a brief background is explored in this chapter about hydrocephalus. It also introduces intracranial pressure and a short review about current methods used in ICP measurements.

### 2.2.1 Intracranial Pressure

Intracranial Pressure (ICP) is defined as the pressure within the cranium and thus in the brain tissue and cerebrospinal fluid (CSF); this pressure is exerted on the brain's intracranial blood circulation vessels. ICP is a dynamic phenomenon constantly fluctuating in response to activities such as exercise, coughing, straining, arterial pulsation, and respiratory cycle. ICP is measured in millimeters of mercury (mmHg) and, at rest, is normally 7-15 mmHg for a supine adult, and becomes negative (averaging -10 mmHg) in the vertical position [106]. Changes in ICP are attributed to volume changes in one or more of the constituents contained in the cranium.

Elevated intracranial pressure (ICP) is a major factor associated with morbidity and mortality in patients with neurological disorders such as head trauma, cerebral stroke, hydrocephalus and brain tumor. The care of hydrocephalus patients can be improved with continuous ICP monitoring. Conventional methods for ICP monitoring are currently limited to patients with severe neurological conditions because of their invasive nature. This is because invasive intracranial pressure (ICP) sensors are potentially dangerous for neurosurgical patients.

### 2.2.2 Hydrocephalus

The human brain is surrounded by a fluid called the cerebrospinal fluid (CSF), that protects it from physical injury, keeps its tissue moist and transports the products of metabolism. This fluid is constantly produced in the parenchyma at rate of approximately 20ml.h$^{-1}$ and drained through granulations near the sagittal sinus. Hydrocephalus is an abnormal buildup of cerebrospinal fluid (CSF) in the ventricles of the brain as shown in Figure 2.1 . The fluid is often under increased pressure and can compress and damage the brain. Hydrocephalus can arise before birth or any time afterward. It may be due to many causes including a birth defect, haemorrhage into the brain, infection, meningitis, tumour, or head injury. Most forms of hydrocephalus are the result of obstructed CSF flow in the ventricular system. The number of people who develop hydrocephalus or who are currently living with it is difficult to establish since there are no national registries or database of people with the condition. However, experts estimate that hydrocephalus affects approximately 1 in every 500 children [43].

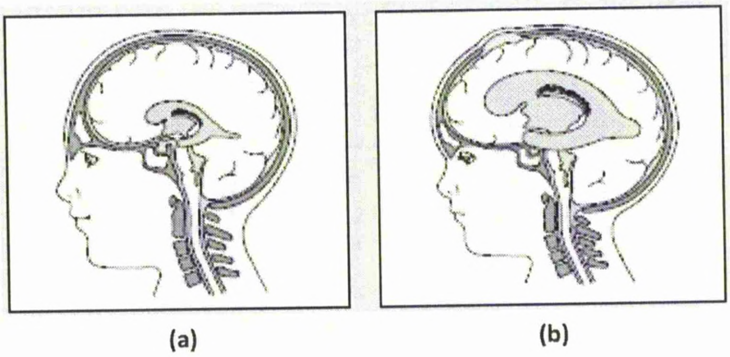



FIGURE 2.1: Change in ventricles size due to hydrocephalus: (a) normal ventricles, (b) hydrocephalus ventricles [62].

Hydrocephalus refers to a condition whereby the volume of the "water" (hydro) in the "head" (cephalus) continually increases. This can lead to one of the two types of hydrocephalus: communicating and noncommunicating. Communicating hydrocephalus, known as non-obstructive hydrocephalus, is caused by impaired cerebrospinal fluid resorption in the absence of any CSF-flow obstruction between the ventricles and subarachnoid space [86]. Non-communicating hydrocephalus, or obstructive hydrocephalus, is caused by a CSF-flow obstruction ultimately preventing CSF from flowing into the subarachnoid space (either due to external compression or intraventricular mass lesions) [86].

This leads to an elevation of the pressure exerted by the cranium on the brain tissue, cerebrospinal fluid, and the brain's circulating blood volume, referred to as intracranial pressure (ICP), and manifests itself in symptoms such as headache, vomiting, nausea or coma. ICP is a dynamic phenomenon constantly fluctuating in response to activities such as exercise, coughing, straining, arterial pulsation, and respiratory cycle. Hydrocephalic patients may experience pressures of up to 120 mmHg. If left untreated, elevated ICP may lead to serious problems in the brain. There is no alternative in most cases to the implantation of a drainage system, known as a shunt.

### 2.2.3 Current Treatment

Since the 1960s the usual treatment for hydrocephalus is to insert a shunting device in the patients CSF system [9]. A shunt is simply a device which diverts the accumulated CSF around the obstructed pathways and returns it to the bloodstream. It consists of a flexible tube with a valve to control the rate of drainage and prevent back-flow. Currently, a mechanical shunt is used to treat hydrocephalus patients. It regulates the CSF flow according to the differential pressure across the valve. This passive operation causes many problems such as overdraining and underdraining. The management of shunt-related problems and disorders has become a de facto subspecialty within neurosurgery. Although it is clear that the treatment of hydrocephalus was vastly improved with the introduction of the differential pressure valve, probably one of the most refractory problems of CSF shunt diversion has been that of overdrainage. Overdraining occurs when the shunt allows CSF to drain from the ventricles more quickly than it is produced. This overdraining can cause the ventricles to collapse. Underdraining occurs when CSF is not removed quickly enough and the symptoms of hydrocephalus recur. These problems may have dramatic effects on the patients such as brain damage.

The next generation of CSF diversion shunts or other treatments for hydrocephalus, will arise from a better understanding of the intracranial hydrodynamics. Intracranial pressure (ICP) is the pressure in the cranium and thus in the brain tissue and CSF; this pressure is exerted on the brain intracranial blood circulation vessels. One of the most damaging aspects of brain trauma and other conditions is an elevated ICP. ICP is measured for the diagnosis and the management of hydrocephalus. Because ICP measurement is of clinical importance, there is considerable interest in finding a noninvasive way to estimate it.

Despite recent advances in valve technology, these shunts do not suit many hydrocephalus patients. This can be realised from the considerable high shunt revision and failure rates: between 30% and 40% of all CSF shunts placed in paediatric patients fail within the first year [2, 89, 90, 114] and it is not uncommon for patients to have multiple shunt revisions within their lifetime.

Shunt systems are not perfect devices and complications often arise. Complications may include mechanical failure, infections, obstructions, and the need to lengthen or replace the catheter. Generally, shunt systems require monitoring and regular medical follow up. The diagnosis of such malfunctions can be both difficult and perplexing even for the experienced clinician.

In 2005, Miethke [68] claimed patent to a hydrocephalus valve with an electric actuating system. This valve would allow improved adaptation to the situation existing in a patient in the case of a hydrocephalus valve. Also the mechatronic valve would add a new option for hydrocephalus shunts that is aiming to treat hydrocephalus not only controlling it.

The principle of controlling such valve is by using a time based schedule. Such schedule would incur many disadvantages, *e.g.* overdrainage/underdrainage, if its selection is arbitrary. In order to optimise the usefulness of such a valve, a method and approach to manage and control such a valve is essential. To eliminate previous disadvantages and make such a valve fully functional, a method is needed to reprogram, modify or replace the time based schedule of this valve dynamically. An intelligent shunting system can be used to autonomously regulate the mechatronic valve according to certain valve schedule and update it based on the intracranial pressure when such data is available. In such a system, ICP readings and other sensory inputs such as patient feedback, would help in tuning the treatment and enabling the intervention of the medical practitioner to update and manually adapt the schedule. In addition, this system can be used to self diagnose its implanted components based on ICP data and valve flow measurements. Such diagnosis would improve the treatment and reduce patient suffering.

## 2.3 Literature Review

The work of other researchers in the area of implanted components and implanted wireless applications are explored in the following sections. Such work helped the author to investigate the requirements and select the suitable components for the proposed system.

### 2.3.1 Implanted Wireless System

In recent decades, implanted wireless systems have been implemented in different medical applications. A short review of these applications is explored below.

Johannessen*et al.* [117] have implemented a telemetry microsystem, that includes multiple sensors, integrated instrumentation and a wireless interface. They employed a methodology similar to that for System-on-Chip microelectronics to design an integrated circuit instrument containing several "intellectual property" blocks. "The present system was optimised for low-power and included mixed-signal sensor circuits, a programmable digital system, a feedback clock control loop and RF circuits integrated on a 5 mm × 5 mm silicon chip using a 0.6 micrometer, 3.3 V CMOS process. The chip, the sensors, a magnetic induction-based transmitter and two silver oxide cells were packaged into a 36 mm × 12 mm capsule format. A base station was built in order to retrieve the data from the microsystem in real-time. The base station was designed to be adaptive and timing tolerant since the micro system design was simplified to reduce power consumption and size. Trials in animal carcasses were carried out to show that the transmitter was as effective as a conventional RF device whilst consuming less power" [117].

Arms and Townsend [8] have summarised the development of wireless strain sensing systems for a variety of customer driven structural health monitoring (SHM) applications. "By combining advanced, two low power microprocessors, flexible software operating modes, and low power signal conditioners, these systems were optimised for very low power operation, while permitting high speed data logging and wireless communications capabilities". They have also described the solutions deploying wireless strain sensors [8].

A wireless, externally powered, implantable device for monitoring of intracranial pressure has been developed by Manwaring *et al.* [41] in the Brain Instrumentation Laboratory at Brigham Young University. "The implantable device is based on low power microprocessor and small dimension pressure transducer conveniently packaged in a biofriendly material. An external interrogator powers and communicates with the subcutaneously implanted device. The developed intracranial pressure monitor system eliminates the need for the battery power supply, and thus avoids the hazards associated with potential leaking of the batteries. Another advantage of the system is its wireless mode of operation. By keeping the interrogator in the close proximity of the patient skull, for example in the patient's pillow, the system can be used for continuous monitoring of the intracranial pressure, even while the patient sleeps. A natural extension of the system is to connect the interrogator to a phone line or data network, the ultimate goal being to enable remote monitoring, logging, and analysis of the intracranial pressure" [41].

The development of a fully implantable micromachined device that uses biotelemetry to monitor beat-to-beat aortic flow through artificial heart valves has been proposed by Sears and John [98]. "The objectives were to demonstrate the ability to acquire and condition data signals with a microcontroller, show the capability to interface the microcontroller to a transceiver IC, RF transmit the acquired data to a PC, and successfully recreate the captured signals with the data received by the PC. The final design is composed of a PIC16C76 microcontroller from Microchip Technologies, Inc., the MicroStamp3 Engine 2.45 GHz transceiver IC, and two AD620 low power instrumentation amplifiers" [98].

Flick *et al.* [36] have showed how a fully implantable stand-by device for measuring intracranial pressure and temperature under normal conditions can be implemented, consisting of a sensor element combined with a transcutaneous telemetric interface. "One of the main points is automatic event recognition, used as a switch between the sampling rates in order to capture special signal component in an emergency situation. Therefore, a signal processing and waveform analysis is exigent, first to control the measured signal online on the portable unit, and second to process the data offline on the stationary unit" [36].

Modern medical solutions to overcome disabilities and diseases tend to increasingly utilize implantable microelectronic systems, which are controlled and monitored from outside the body have been illustrated by Hitzelberger *et al.* [41]. "One example is the electrical stimulation of nerves which have lost their natural functionality by an accident. This ASIC was developed as the central component in implantable, batteryless electro-neural stimulation systems. The first application being an implant for restoring basic movement abilities of a disabled hand, caused by a spinal cord injury. It allows stimulation of nerves with two independently controlled currents on one or more of 12 neural electrodes. The system is controlled and powered using an 80kBit/s transcutaneous RF telemetry link. The on-chip microcontroller was optimised to perform multi-tasking protocol handling and signal processing at a low-power level. The ASIC provides an 8-bit ADC to secure the integrity of the stimulation subsystem before activating, and a low speed load-shift keying RF-link to transfer protocol and measurement data to the external device" [41].

Kit Yee Au-Yeung [121] has described the design, implementation, and evaluation of an implantable cardiac telemetry system developed for the long-term study of atrial fibrillation (AF) and anti-tachycardia pacing (ATP) in conscious and ambulatory animals. "By building a pacing and sensing system with remote interrogation and real-time transmission of atrial electrograms (AEGs), this system yields valuable results that cannot be obtained in an acute surgical setting or by using commercial implantable cardioverter-defibrillators. This novel system was designed to provide the following capabilities for AF research in conscious, untethered animals: chronic rapid atrial pacing for AF induction, programmable stimuli for atrial effective refractory period (AERP) measurements, conventional ATP, and real-time telemetry of 4 channels of AEGs. The resulting system consisted of an implantable unit that paced and sensed from the atria and an external communication unit with a graphical user interface that remotely controlled the pacer and displayed" AEGs [121].

Winfried Mayr *et al.* [61] have distinguished three generations of FES implants for activation of neural structures: RF-powered implants with antenna displacement dependent stimulation amplitude, RF-powered implants with stabilised stimulation amplitude, and battery powered implants.

The work of Wentai Liu *et al.* [60] targets devices such as visual prostheses that can restore eyesight to the blind, functional neuromuscular implants that can restore motor mobility to paraplegics, and cortical implants that can enable brain-machine interfaces. "Besides replacing lost biological functionality, implantable wearable microelectronics could potentially augment existing human visual and auditory capabilities and provide a more effective human-machine interface. The system replaces the functionality of vision in blind patients affected by retinitis pigmentosa and age-related macular degeneration" [60].

A miniature telemetric pressure-measuring system is presented by Chatzandroulis *et al.* [21] The system uses passive telemetry to transfer power to the transponder and pressure data to the remote base unit. "A novel capacitive-type pressure sensor based on an SiGeB diaphragm is used as a sensing element. The merits of combining a capacitive pressure sensor and passive telemetry lies in the inherent low-power consumption of the sensor and the continuous availability of power through induction. The pressure sensor is connected to an integrated interface circuit, which includes a capacitance to frequency converter and an internal voltage regulator to suppress supply voltage fluctuations on the transponder side. In addition, the sensor and accompanying interface circuit take up very little space so as to be suitable for implantation" [21].

### 2.3.2 Pocket PC

Nagl *et al.* [82] have summarised the advantages and disadvantages of using a WinCE PocketPC as a central controller and computational platform. It is used to acquire and process medical data in an ambulatory telemonitoring environment. Additionally, they used the Bovine Mobile Observation Operation (BMOO). The BMOO system is a veterinary telemonitoring system designed to monitor cattle state of health wirelessly [82].

Norio Nakata *et al.* [83] have developed a novel mobile system for use by radiologists in managing Digital Imaging and Communications in Medicine (DICOM) image data. The system consists of a mobile DICOM server (MDS) and personal digital assistants (PDAs), including a Linux PDA with a video graphics array

(VGA) display. "The MDS has a 60-GB hard disk drive and a built-in wireless local area network (LAN) access point, and supports a DICOM server (Central Test Node). The Linux-based MDS can be accessed with personal computers (PCs) and PDAs by means of a wireless or wired LAN, and client-server communications can be established at any time. DICOM images can be displayed by using any PDA or PC by means of a Web browser. Simultaneous access to the MDS is possible for multiple authenticated users. This wireless system allows efficient management of heavy loads of lossless DICOM image data and will be useful for collaborative work by radiologists in education, conferences, and research" [83].

### 2.3.3 Implants

The need for implanted medical systems that autonomously perform their tasks, has urged the development of implanted components, *e.g.* microcontroller, transciever, valves, batteries.

Liang *et al.* [59] have presented a study of an implantable microcontroller-based bi-directional transmission system with an inductive link designed for biological signal sensing. "The system comprises an external module and an implantable module. The external module incorporates a high-efficiency class-E transceiver with amplitude modulation scheme and a data recovery reader. The transceiver sends both power and commands to the implanted module, while the reader recovers the recorded biological signal data and transmits the data to a personal computer (PC) for further data processing. The implanted module was successfully verified in animal experiment". Their study confirms that the proposed biological signal sensing device is suitable for various implanted applications following an appropriate biocompatible packaging procedure [59].

In December 2003, an EU programme, Healthy Aims [88], was launched to address main issues of implanted, microsystems medical devices. "This arose from the European microsystems network, NEXUS Medical Devices Group and led to a 26 partner team from nine countries participating in this ambitious and cross disciplinary project. The range of technologies and target products are as follows: RF communications suitable for implanting into the human body, implantable power sources, biocompatible materials, micro-electrodes to connect the power source to nerves Micro-assembly techniques for 3D, flexible structures requiring coating with biomaterials, and sensors and actuators to fit inside the body" [88].

#### 2.3.3.1 Microcontroller

A microcontroller-based multichannel telemetry system suitable for in vivo monitoring of physiological parameters was described by Valdastri *et al.* "The device can digitalise and transmit up to three analog signals coming from different sensors. The telemetry transmission is obtained by using a carrier frequency of 433.92 MHz and an amplitude-shift keying modulation. The signal data rate is 13 kb/s per channel. The digital microcontroller provides good exibility and interesting performance, such as the threshold monitoring, the transmission error detection, and a low power consumption, due to the implementation of a sleep mode. The small overall size (less than 1 $cm^3$), the power density compatible with current regulations for the design of implantable devices, and the dedicated packaging make the system suitable for in vivo monitoring in humans". They also described an in vivo pressure monitoring case study [64].

Neihart and Harrison have developed micropower integrated circuits to be implanted near the brain for recovering clock and data signals over a transcutaneous power link. "The data recovery circuit produces a digital data signal from an AC power waveform that has been amplitude modulated. They have also developed an FM transmitter with the lowest power dissipation reported for biosignal telemetry. The FM transmitter consists of a low-noise biopotential amplifier and a voltage controlled oscillator used to transmit amplified neural signals at a frequency near 433 MHz. All circuits were fabricated in a standard 0.5-mm CMOS VLSI process. The resulting chip is powered through a wireless inductive link. The power consumption of the clock and data recovery circuits is measured to be 129 mW; the power consumption of the transmitter is measured to be 465 mW when using an external surface mount inductor. Using a parasitic antenna less than 2 mm long, a received power level was measured to be 59 73 dBmat at a distance of one metre" [84].

#### 2.3.3.2 Valves

Miethke [67] has demonstrated the available shunt-systems for the treatment of Hydrocephalus. These shunt-systems are exclusively based on simple mechanical principles. In comparison to pacemakers or other sophisticated medical devices shunt-technology is said to be "old-fashioned" and the introduction of electronical intelligent systems should be a second remarkable breakthrough after the introduction of the first shunts in the beginning of the fifties. The decisive question is how far an electronically controlled device can present new possibilities for the treatment without a significant increase of new risks. All available shunt-systems are operating depending on the pressure difference between the ventricular system and the abdominal cavity or the atrium of the heart. The used mechanical principles react to changes of this differential pressure. The goal is to re-establish physiological pressure values in the ventricular system of the patient. The obvious solution to control the intraventricular pressure (IVP) electronically is the opening and closing of the device depending on the actual measured IVP. But this simple approach leads to severe unsolved technical problems like long-term drift and general accuracy. It is a matter of controversy whether a shunt system should re-establish a certain IVP, a certain ventricular size or possibly a certain condition of the brain tissue. However, the main purpose of a drainage is the withdrawal of CSF from the ventricular system. The amount might be depending on changing individual conditions or on age, on the height of the patient or on the kind of hydrocephalus. The introduction of an electronically controlled programmable switch presents new perspectives for the diagnosis, the general understanding and the therapy of hydrocephalus. The switch works without a pressure transducer. The device is programmed by a physician who determines at what time during the day or the night the shunt is open or closed. The shunt can be closed at any time non-invasively or it can be programmed to be always open. The telemetric programming allows any kind of individual adaption [67].

#### 2.3.3.3 Battery

EaglePicher Medical Power [33] has announced the successful development of the industry's smallest implantable-grade medical battery. "The battery's size and shape (cylindrical, 0.260″ long × 0.090″ diameter) enables a device so small that it can be deployed via a minimally-invasive catheter procedure rather than traditional implantation surgery. The device is presently undergoing clinical trials in Europe. The Micro Battery, which is at least 50% smaller and lighter than known commercially available products, is based on a proprietary new cell construction developed by EaglePicher Medical Power. Electrical capacity exceeds the original design objective by a factor of five with the result that it can theoretically power the device for more than 15 years. The Micro Battery will create new opportunities for device manufacturers in Neurological Catheters, Cardiovascular Monitoring, and Neural Prostheses (Retinal implants, Cochlear Implants)" [33]. Argonne National Laboratory (ANL) [92] are developing an implantable batteries. "These rechargeable batteries can recharged wirelessly from external power supply via RF [104], which are 100 times smaller than a standard AA battery, can power implantable microstimulator systems designed to help patients with neurological disorders, such as Parkinson's disease, or muscular impairments.

## 2.4 External Shunting System

The external shunting system components were selected by the author based on the system requirements. In addition, the initial functionalities of the external part has been decided and listed below.

- Allow the user to control the state of the internal valve, via the Windows Mobile interface.
- Allow, via the same interface, the user to query the internal pressure transducer and view logs/plots of ICP activity over extended periods.
- Use implantable pressure transceducer to read intracranial pressure (ICP), pass it to the implantable microcontroller and send it out to the external patient device for analysis.
- The system would be able to autonomously open or close the implantable valve according to the valve program.
- The implantable system would have the ability to receive any external signal from the external patient device that will be used to open or close the valve in emergency cases.

- The external patient device would be able to access the central database (send or receive any important data) through mobile communication.
- The external patient device would be able to make any update on the internal valve program wirelessly by using RF transceiver.
- Patient directly input his feedback into the external patient device.
- The external patient device would have the capability of intelligently analyse sensory inputs (patient feedback, intracranial pressure reading) in order to decide whether there is a need to update the valve schedule.

The main components of the external shunting system are as follow.

- MSP430X microcontroller which would be used to pass a signal or data to the ZL70101 RF transceiver (external RF). In addition, it is used to pass a signal or data which is received from the RF transceiver to the patient device.
- ZL70101 RF transceiver which would be used to send or receive the signal or data to/from the implantable ZL70101 RF transceiver (internal RF).
- The patient device which would be used to save and execute intelligent software which is responsible for many functions such as sending an emergency signal to the implantable microcontroller, updating the implantable program, etc. In addition, used to send or received any emergency signal or important data to/from the hospital database. Also, the graphical user interface would be used by the patient or doctor to communicate with the implantable system and with hospital database.

## 2.5 Implantable Shunting System

Many factors have been taken into consideration for selecting the implantable shunting components (*i.e.* microcontroller, transceiver and the battery) such as power consumption, size and compatibility with Medical Implantable Communication Standards (MICS).

There are many characteristics that should be taken into consideration when implantable microcontroller and transceiver will be implanted inside the human body. The most important physical parameters are size, type of material (that should be compatible with the human body), power consumption and high efficiency. Also, there are other logical or functional parameters, such as compatibility with FCC and MICS. The Medical Implant Communications Service (MICS) is an ultra-low power, unlicensed, mobile radio service for transmitting data in support of diagnostic or therapeutic functions associated with implanted medical devices. The US Federal Communications Commission (FCC) allocated 402-405 MHz frequency band for MICS operations on a shared, secondary basis in 1999. Although it is a fairly new standard, its usage is rapidly increasing in medical implant devices such as cardiac pacemakers, implantable cardioverter defibrillator, neurostimulators, hearing aids and automated drug delivery systems [54]. Also, there are many challenges that should be considered when the components of implanted medical devices would be selected, such as the following basic requirements:

- Low power consumption during 400 MHz communication is required. Implant battery power is limited, and the impedance of implant batteries is relatively high. This combination limits peak currents that may be drained from the supply. During communication sessions, current should be limited to <6 mA for most implantable devices [122].

- The transceiver must operate in a low-power sleep mode, with the capability to look periodically for a wake-up signal.

- Minimum external component count and small physical size are important factors *i.e.* an RF module for a pacemaker must be no larger than $5 \times 5 \times 10$ mm. Furthermore, implant-grade components are expensive, and using high levels of integration may significantly reduce costs. Integration has the additional benefit of increasing overall system reliability.

- Reasonable data rates are demanded; pacemaker applications are currently demanding >20 Kb/sec, with higher data rates projected for the future.

- High reliability in both data transmission and system operation.

- An operating range is typically >2 m because the MICS band is designed to improve upon the very-short-range inductive link. Longer operating ranges imply that good sensitivity is needed, because small antennas and body loss affect link budget and allowable range. Antenna matching and body loss can typically be more than 40 dB.

## 2.6 Components Selection

Filtration process has been done between different microcontrollers and between different types of RF transceivers. As a result of this process, the suitable implantable microcontroller and RF transceiver for the application of this research have been selected and the comparison operations summary are shown in Tables 2.1 and 2.2.

TABLE 2.1: Comparison summary for different microcontrollers

| Microcontroller | EM6812 | M68HC II | MAXQ2000 | MSP430X |
|---|---|---|---|---|
| Power consumption | 120µA Active<br>0.8 µA standby<br>0.16 µA sleeping mode | 500 µA Active,<br>20 µA standby,<br>10 µA sleeping mode | 19.2 mA Active,<br>55 µA standby,<br>55 µA sleeping mode | 200 µA Active<br>0.7 µA standby,<br>0.7 µA sleeping mode |
| Memory size | 1 KB RAM<br>64 KB flash | 1 KB RAM<br>24 KB EPROM | 2 KB RAM<br>64 KB flash | 10KB RAM<br>64 KB flash |
| Availability of EV. Kit | Yes | Yes | Yes | Yes |
| Availability of Emulation tools | Yes | Yes | Yes | Yes |
| Applications | Body care | Body care, medical instruments | Medical instruments | Medical instruments |
| Other | 8-bit | 16-bit, 51 instructions | 8-bit | 16-bit, 31 instructions |

TABLE 2.2: Comparison summary for implantable RF transceivers.

| Transceiver | AMIS 5300 | TRF6903 | ASTRX2 | SUBQORE | ZL70101 |
|---|---|---|---|---|---|
| Standard compatibility | MICS | FCC | FCC, ETSI | FCC, ETSI, MICS | MICS,FCC, IEC |
| Operating current | 12 mA RX<br>30 mA TX | 15-23 mA RX<br>15-40 mA TX | 7.5 mA RX<br>25 mA TX | 1.7 mA Peak | 5 mA RX/TX down to < 1mA |
| Sleep current | 1 µA | 4 µA | 0.5 µA | 14 µA | <0.25 µA |
| Supply voltage | - | 2.2-3.6 v | 2.5-3.6 v | - | 2.1-3.5 v |
| Channels | 9 channels<br>402.3-404.7 | Medical ISM band | - | 402-405 MHz | 402-405 MHZ (10 MICS)<br>433-434 MHz (2 ISM) |
| Applications | Implantable medical applications | Personal and handheld medical diagnostic, medical instruments. | Medical instruments | In body Medical diagnostic | Implantable medical application |
| Mode | - | - | - | Implantable Base station | Implantable Base station |
| Data rate | 1-19.2kbps (OOK)<br>2-128kbps (FSK/GFSK) | Up to 64kbps | 19.2 kbps | 400 kbps | High data rate (800/400/200 kbps) |

### 2.6.1 ZL70101 RF Transceiver

As a result of comparing different transcievers, Zarlink's ZL70100 medical implantable RF commercial grade transceiver was selected for reason explained below. Zarlink's ZL70100 medical implantable RF commercial grade transceiver chip is the first device designed exclusively for wireless communication systems that link implanted medical devices and base stations [122]. Merging RF and ultra low-power expertise, the ZL70100 base station chip operates in the MICS 402 - 405 MHz service band and the 433 - 434 MHz ISM band. Supporting leading data transmission rates while consuming less than 5 mA of current, the ZL70100 chip allows implanted devices to quickly transmit patient health and device performance data without impacting the useful battery life of the implanted device. An integrated ultra-low power wake-up RF receiver further extends battery life. A highly integrated device, the ZL70100 requires just two external components (excluding antenna matching), allowing manufacturers to use board space savings to increase battery size and support advanced functionality while lowering BoM (Bill of Material) cost. A simplified block diagram of ZL70100 is shown in Figure 2.2.

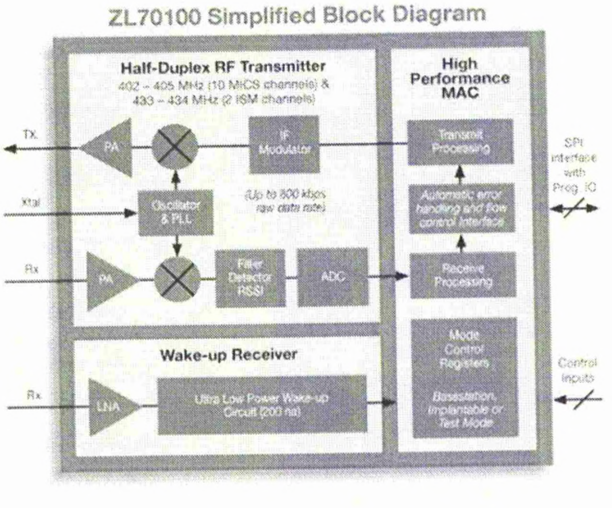



FIGURE 2.2: A simplified block diagram of ZL70100 [122].

#### 2.6.1.1 Typical Applications

The typical applications of ZL70100 transceiver as noticed in [122] are follow.

- Implantable medical devices, including pacemakers, ICDs (implantable cardioverter defi-brillators), neurostimulators, implantable insulin pumps, bladder control devices, implantable physiological monitors.
- Short-range Body Area Network (BAN) applications using 433 MHz ISM band.
- The ZL70100 transceiver chip is a half-duplex RF communication link specifically designed for MICS communication systems. Supporting data rates up to 800 kbps for raw data and 500 kbps for usable data, the chip quickly transmits large amounts of patient and performance data. The ZL70100 includes an integrated MAC, providing complete device control along with forward error correction and error detection.
- Battery life is a critical performance parameter for implanted devices. The ZL70100 transceiver's innovative RF wakeup receiver allows the chip to operate in a low-current (200 nA) "sleeping mode". Communication between implanted and base station transceivers is then initiated a specially coded wakeup signal from the 2.45 GHz base transmitter. Alternative wake-up mechanisms using 400 MHz or direct wake-up by an IMD processor are also supported. The ZL70100 can be used in implantable device communication systems shown in Figure 2.3, as well as in- and on-body devices used in BAN applications.

#### 2.6.1.2 Features

- 402-405 MHz (10 MICS channels) and 433-434 MHz (2 ISM channels).

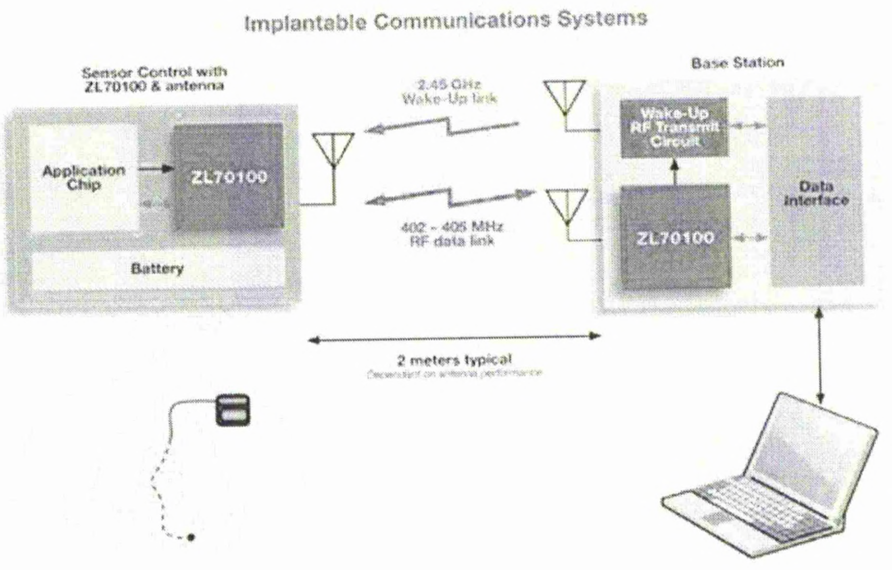



FIGURE 2.3: The ZL70100 in implantable device communication systems[122].

- High data rate (800/400/200 kbps raw data rate).
- High performance MAC with automatic error handling and low control, type < 1.5x10-10 BER.
- Very few external components.
- Extremely low power consumption (5 mA, Continuous TX/RX, <1 mA low power mode).
- Ultra low power wakeup circuit (200 nA).
- Standards compatible (MICS, FCC, IEC).

### 2.6.2 MSP430x Microcontroller

The main objective of designing the MSP430 microcontroller was to focus on the ultra-low power consumption of the complete system. The goal was to create a microcontroller which consumes very little current in the sleep modes and performs the given tasks in the active mode as fast as possible. In order to reduce the current consumption of the proposed system, the MSP430 allows the ability to influence the active current consumption and active time as well as sleep mode current consumption and sleep time. The active mode current consumption of the MSP430 is 400 $\mu$A in a typical 3-V system. The time to wake-up from the sleep mode to a total functional system takes a maximum of 6 $\mu$s. This allows the MSP430 to be in sleep mode longer and eliminates unnecessary energy use in the active mode. The powerful 16-bit CPU core ensures a fast execution of the tasks and therefore reduces the active time. This achieves that the higher the performance of the CPU, the lower the system power consumption. In addition, the peripheral modules are specially designed to support these ultralow power features. The sleep modes offer a reduced current consumption even when some peripherals are still active. For example, in a simple real time clock (RTC), it is not necessary to keep the device in active mode. Another example, the system can operate from the 32-kHz (ACLK) clock instead of 1-4 MHz (MCLK) with the timers and LCD still active. These examples are benefits of the most often used low-power mode 3 (LPM3) which consumes 1.3$\mu$A typically. The current consumption can be reduced down to 0.1$\mu$A in LPM4 where the MSP430 is still capable of processing external interrupts. In summary, several low power modes are supported, which balance the needs of different applications as follow [110].

- Active mode:- CPU is active, all enabled clocks are active.
- LPM0:- CPU and MCLK are disabled, SMCLK and ACLK are active
- LPM1:- CPU, MCLK, DCO osc. are disabled, SMCLK and ACLK are active.
- LPM2: - CPU, MCLK, SMCLK, DCO osc. are disabled, DC generator and ACLK are active

- LPM3: - CPU, MCLK, SMCLK, DCO osc., DC generator are disabled, ACLK is active.
- LPM4: - CPU and all clocks disabled.

The main key features of the MSP430 family include:

- Ultralow-power architecture extends battery life.
- 0.1$\mu$A RAM retention.
- 0.8$\mu$A real-time clock mode.
- 250$\mu$A / MIPS in the active.
- High-performance analog ideal for precision measurement.
- 12-bit or 10-bit ADC - 200 Kilo Samples Per Second (ksps), temperature sensor, VRef.

### 2.6.3 Mechatronic Valve

One of the recent advances in the management of hydrocephalus is the invention of a mechatronic valve. The desirability of such a valve lies in the potential of having a shunt that not only controls hydrocephalus but also seeks to treat it. In contrast to current valves, such a valve (mechatronic valve) is regulated based on a time based schedule not on the differential pressure across the valve. Thus the effectiveness of such a valve is highly dependant on selecting an appropriate valve schedule that delivers personal treatment for every individual patient. Providing such a schedule is likely to be one of the obstacles facing the implementation of the mechatronic valve.

The mechatronic valve compromises an electrical switching valve which can be adjusted by the electrical actuating system between an open and a closed positions, wherein the switching valve is stable at these positions when the electrical actuating system is not activated, such that no energy is required to maintain the closed and open positions [67].

The mechatronic valve consists of a spherical valve body which in the closed position rests in a sealing manner on a valve aperture and in the open position rests in a recess laterally adjacent to the valve aperture. Figure 2.4 shows a schematic longitudinal sectional view of a bi-stable mechatronic valve [67]. An electronic system is supplied with power by a battery. Depending on switching direction, a current is applied to a coil, so a magnetic field is generated which moves a slide. The slide can adopt two different rest states, which are secured by a spring. The spring would secure the seat of a sphere even in the case of vibrations and keep the force to displace the sphere small. The valve outlet is a hole that has a diameter around 1 mm, corresponding to the internal diameter of a typical drainage tube. The sphere is preferably produced from a hard and light material (*e.g.* aluminum oxide ceramic) and it should have a diameter that is three times greater than the hole of the valve outlet. Thus if it is pushed over the hole, then the drainage would be closed. And if pushed into the position of the blind hole, then the total cross-section of the hole is exposed, thus minimising the danger of blockage. The position of the slide can be continuously detected by a detector [67].

The slide of the mechatronic valve is controlled by a time based schedule. The schedule would be simply the distribution of the valve status (open/close) over time. Such schedule would incur many disadvantages *e.g.* over-/under-drainage, if its selection is arbitrary. The size of the device is similar to pacemakers and would be implanted in the chest of the patients. The advantages of the new device

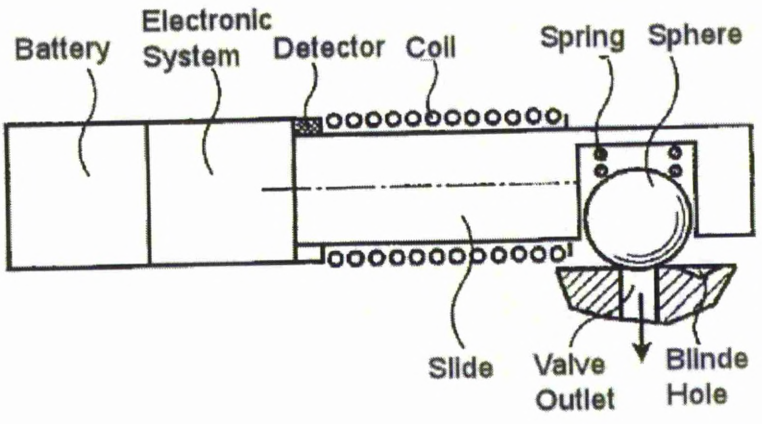



FIGURE 2.4: A schematic longitudinal sectional view of a bi-stable mechatronic valve [67].

might be counterbalanced by the drawbacks like the big housing needed or the new risks [73].

### 2.6.4 ICP Sensor

The main aim of adding an implantable intracranial pressure sensor to the proposed shunting system is to monitor quality and functionality of the mechatronic valve. In addition, in order to reduce the hospitalisation of patients to a minimum of days. Implantable sensors provide a cost saving alternative for monitoring and allow the patient to continue participating in his or her everyday life. Also, continuous monitoring of intracranial pressure is desired to evaluate the function of the shunt system over time and detect any fault. Based on this, implantable pressure sensors will be of significant value for cost-effective continuous monitoring of intracranial pressure even under everyday life conditions.

Many researchers have worked on designing and producing such ICP sensor to use in treatment and monitoring of hydrocephalus patients. The ICP sensor that was suggested for the proposed shunting system is selected for its suitability for long-term monitoring of pressure in the brain cavity.

Ampus Micro Technologies [17] has produced ICP prototypes, which have shown excellent stability over a 30-day period in lab trials. Thirty days is the critical performance requirement for short-term applications. Animal trials are planned at the UK North Bristol National Health Systems Neurosurgery Department

ISSYS wireless pressure technology will provide safe, continuous intracranial pressure measurements, and supports the trend towards home health monitoring and improvement in-patient diagnostic care, with the potential to revolutionise the way hydrocephalic and brain trauma patients are treated. The pressure monitoring system consists of two major parts: an implantable, batteryless, telemetric sensor and a companion hand-held reader [45].

Hodgins et al. [42] have developed an ICP sensor system which is suitable for short- or long-term monitoring of pressure in the brain cavity. Short-term monitoring applies, for example, to people who have suffered head trauma in an accident and are in intensive care. Long-term monitoring applies to people suffering with hydrocephalus who are treated with a shunt for draining excessive fluid.

The most important features that would be taken into consideration when the implantable intracranial pressure sensor will be selected is that such sensor must be extremely stable, small and safe over time. Figure 2.5 shows the selected very small pressure-sensor head (diameter 3mm) for the proposed shunting system. The sensor would receive its power from the implanted battery and it would be controlled by the implanted microcontroller.

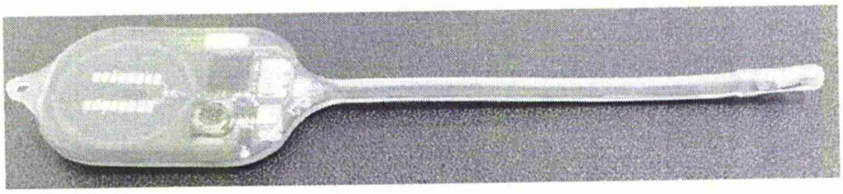


FIGURE 2.5: A prototype of the selection ICP sensor system [42].

### 2.6.5 Implantable Flowmeter

Shunt systems are not always reliable. Although the introduction of programmable valves has improved their dependability, under/over-drainage of the ventricles is not uncommon. A feedback device such as an implantable flowmeter is necessary to provide important information e.g. to what extent should the shunt valve should be programmed to drain excess CSF. It will also measure CSF flow to verify that the shunt system is working properly and not causing harm to the patient. At this time there is no flowmeter small enough or accurate enough for this purpose. The flowmeter indicates different flow rates by producing a voltage measure. The flowmeter is sensitive at low flow rates (below 1.8 ml/min) but there is a saturation point at higher flow rates (above 2 ml/min).

A flowmeter system was selected to be used as a part of the proposed shunting system to measure low flow rates as shown in Figure 2.6.

This flowmeter system would help us to create a smart shunt for hydrocephalus patients by giving an indicate whether the CSF is flowing through the shunt or not.

### 2.6.6 Implantable Battery

The most important challenge for the implantable devices is power consumption. Unlike many consumer products, batteries in implantable medical devices can not be replaced. The implantable medical devices can be classified into two types:

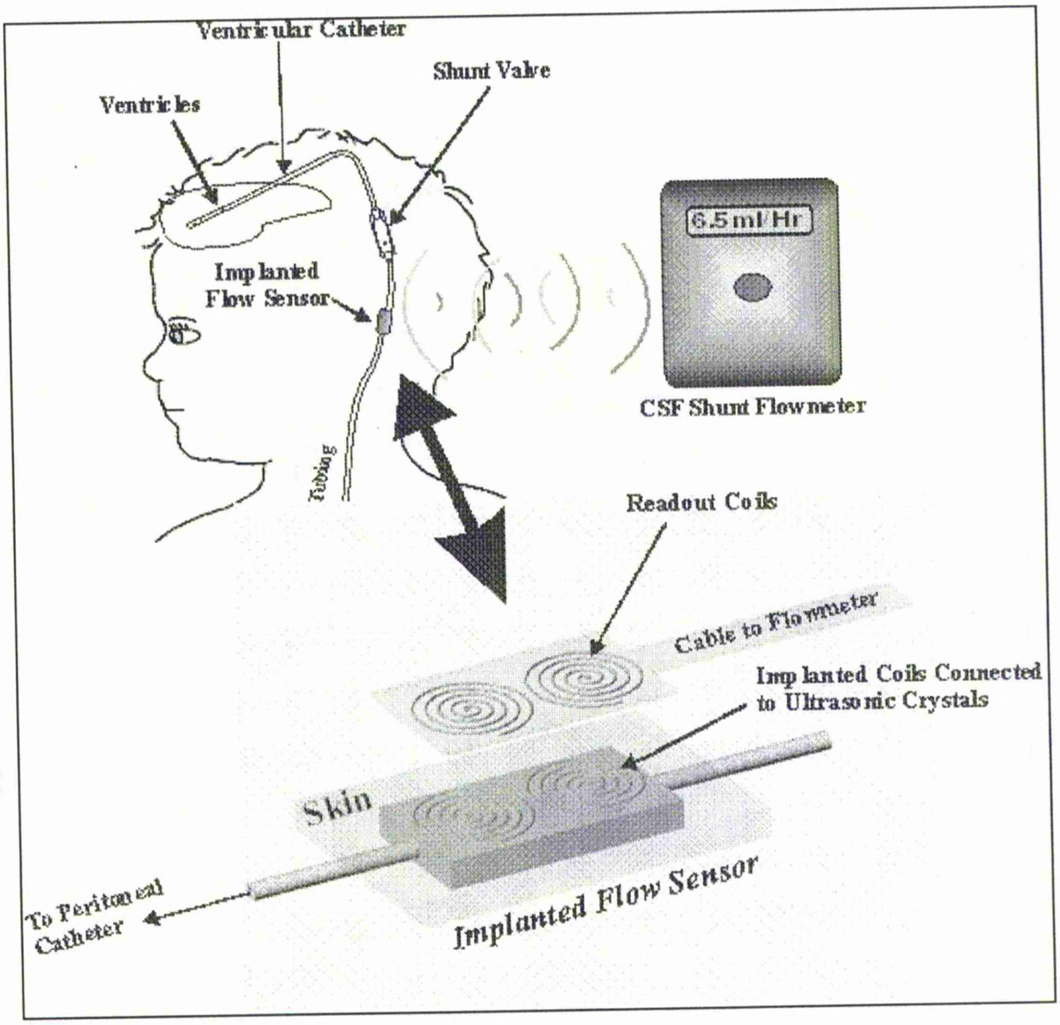



FIGURE 2.6: A prototype of the selected flowmeter system [111].

passive or active. The active devices require power to execute or to operate their functions. Power to these devices has been supplied by two methods, the first method using internal implantable battery integrated to the device. The second method using external power source depends on a wireless RF transceiver [104]. Nowadays, many companies produce a suitable power source to solve the implantable devices power problem. There are many options of implantable batteries that can be selected to be implemented in the proposed system. The main criteria for selection are high capacity and small size. After a thorough investigation, QHR has been selected for many reasons such as; it is used in many implantable medical applications like drug-infusion, cardiac-pacing device requirements. Also, the size (24.5 $\times$ 7.7mm) and weight (10.5g) of this battery are suitable for this application. In addition, the QHR capacity is 950mAh, which make it suitable for many implantable medical applications [44]. It is essential in such an application to illustrate the principle of battery capacity as well as calculate the power needed for such system to work for long life and this is explained as follow.

#### 2.6.6.1 Battery Capacity

A battery is a device used to store chemical energy and makes it available in an electrical form. In addition, there are many specifications of batteries such as life span, charge rate, temperature range, charge and discharge temperature range, cycle life and more. One of the important features that need to be understood and analysed is the battery capacity. The amount of current that is supplied from the battery to any electrical devices within period of time is called the capacity of the battery and it is measured in Ampere-hour [94]. The available capacity of the battery depends upon the rate at which it is discharged. If the battery discharged at high rate, the available capacity will be lower than expected. Therefore, a battery rated at 950mAh will supply 95mAh over a 10hour period [78]. The relationship between current, discharge time and capacity of battery is expressed by Peukert's law. Peukert's equation is usually written as [100]:

$$I^n \cdot T = C \tag{2.1}$$

where,

I is the discharge current in Ampere, T is the time in hour, C is the capacity of the battery, and n is Peukert's exponent (has a value between 1 and 1.2 depend upon rating).

#### 2.6.6.2 Calculation of the Power Consumption

The proposed system has four components that need power from the battery to execute their functions. The first component is the flowmeter and due to the fact that its information is not available, it is difficult to calculate the power needed for this component in the proposed application. The second one is the valve or the switch. The main function of this part is to open (allow the CSF liquid to drain out of the brain) or to close (to block the CSF liquid draining out of the brain). Therefore, these operations depend upon many factors such as the output of intelligent software, the patient feedback, the physician and finally the sensor inside the brain.

1. Valve Power Consumption:

   To calculate the power consumed by the valve, the duration time for each open and close period of the valve should be calculated. In addition, the number of times that should be open within specific period of time should be estimated. Estimating this number is not an easy task due to the fact that there is no enough clinical data for the people who have hydrocephalus. Thus, many questions need to be answered to estimate it. The first question is, how many times the valve should be open every day. The second question is, what is the duration of each on and off period. The last question is, how much the value of current needed to open or close the valve?

   Calculations of power consumption were based on the clinical data (*i.e.* ICP traces) taken for two patients who have a hydrocephalus problem. The first patient's ICP charts has been recorded for 11 hours and 38 minutes started from 22:06 and ended on 9:44. The data has been recorded while the patient is in a lying position. After studying and analysing this ICP charts, the following observations have been made.

- The value of ICP in normal range is between 10-15mmHg while patient in lying position.
- ICP increased above 15mmHg at 23:55 for 50 minutes then returned back to the normal range.
- Range increased again above 15mmHg for 50 minutes at 1:30.
- At 3:25 the range continued increasing above normal range till 4:45 and the maximum value of the ICP was 50mmHg.
- When ICP is increased above normal range for short periods of time (less than 30 minutes), it was not considered as abnormal since it is transient increase which could be due the sneezing or cough.

For this patient, the duration of time needed to open the valve is calculated (180 minutes).

On the other hand, the second patient's ICP charts are completely different. The data have been recorded for 20 hours while patient was lying. The recorded data was not clear and it was difficult to perform calculations based on it. By observing the charts the period of time when the values of ICP are more than 15mmHg is between 10-12 hours. Based on these charts, the period of time needed to open the valve for first patient is 180 minutes out of 12 hours. While the duration for which the valve should be open for the second patent is 420 minutes out of 12 hours. The average of the two cases is (420+160)/2=265 minutes. In seconds per year it equals 265 min $\times$ 60 (sec/min) $\times$ 2 $\times$ 365 (day/year) = 11607000 sec. The daily number of times needed to toggle the valve state (on-off or off-on) for the two patients are 6 times for first patient and 24 times for the second patient. The average is (24+6)/2=15 times per day. The number of times per year equals 15 (time/day) $\times$365 (day/year) = 5475. The current needed for the valve to open or close is assumed to be 1 $\mu$ A.In addition, the time needed to open/close is assumed to be 1 second. Then the value of capacity needed for the valve to do it's function for 15 years is given in the following equation,

$$I \cdot T = C \tag{2.2}$$

Knowing that $I = 1$ ,

T=15 $\times$ 365(day/year) $\times$ 15 = 82125 second, N=1, then C = 0.001 mA$\times$ 82125 second = 82.125 mAs for the 15 years.

The estimated capacity of power needed for the valve to work in the application for 15 years based on the studied case is 82.125mAs for 15 years. The disadvantage of this calculation is the sample size. The main aim of this calculation is to estimate the power needed for the valve in both worst and best hydrocephalus patient case.

2. Transceiver Power Consumption:

   The main function of ZL70100 transceivers is to send and receive the data during two stages. In the first stage, it sends the initial programme or any update for the programme to the implantable MS430X microcontroller. In addition, it sends the patient's signal or doctor's signals to open or close the valve through microcontroller. In the second stage, it sends the clinical data or any feedback from the implantable MSP430X microcontroller to the external station. In order to calculate the power needed for ZL70100 in the proposed system, the amount of data that will be sent or received by the transceivers and the speed of the ZL70100 (*i.e.* data rate) during data transfer should be known. The maximum size of the data to be transferred depends on the microcontroller flash memory size. The MSP430X flash memory size is 1-120kb and the ZL70100 minimum data rate is 200kbps. The time needed for ZL70100 to transfer the maximum data size (120kbyte) is given in the following equation.

$$S = T \cdot R \tag{2.3}$$

where,

T is the time needed to transfer the data size, S is the size of data, and R is the data rate.

For the proposed system, S equals 120 (kbyte) $\times$ 8 (bit/byte)=960 kbit. R=200 kbps. Then T =960/200=4.8 second.

The total time needed to transfer the maximum size of data is 4.8 second. Next, the number of times the data will be transferred per year need to be known. And this limited by the amount of battery capacity available. The data transfer operation is assumed to happen four times per month. Then the total power needed for transceiver in this application to perform its tasks in active mode for 15 years is calculated as follows.

Total capacity = 5 (mA) $\times$ 4.8 (sec) $\times$ 4 (time/month) $\times$ 12 (month/year) $\times$ 15 (year)

= 17280 mAs for 15 years.

where,

Duration for each transfer equals 4.8sec, ZL70100 operating current equals 5mA, number of times per month equals 4, number of months per year equals 12, and application estimated cycle life is 15 years.

On the other hand, The total capacity needed for ZL70100 transceiver in this application for a cycle life of 15 years in sleeping mode is given in the following equation.

Total capacity = 250nA $\times$(60$\times$60$\times$24$\times$365$\times$15)-(4.8$\times$4$\times$12$\times$15).

Total capacity $= 250nA \times (473040000 - 3456s)$

Total capacity = 118259.136 mAs for 15 years.

As a result of the above calculations, total capacity needed for ZL70100 in both active and sleeping mode for a cycle life of 15 years in this application is 122576.136 mAs.

3. Microcontroller Power Consumption:

   The main functions of MSP430X microcontroller are receiving the updated schedule from external station, processing the internal programme which will be saved in the flash memory and used to control the open/close valve operation, saving the state of valve in the flash memory, receiving an emergency output signal from external unit, taking suitable decision, receiving a pressure sensor signal, saving it in the flash memory (routinely/emergency case), and finally sending the data stored in flash memory to the external station when this data will be quote. The sleeping, standby and active periods of time for a cycle life of 15 years need to be calculated.

   There are many cases where microcontroller are in active mode such as, time needed to receive and send data from/to external station, time needed to send a signal to open /close the valve, time needed to receive a signal from pressure sensor and save it, time needed to update the internal programme, time needed to execute intelligent software, time needed to save any update in the flash memory and finally time needed for software library access operation. Thus their number and periods are needed to be known. The power needed for triggering the opening/closing of valve and the power needed for sending/receiving the data from/to external station have been calculated and in previous equations.

On the other hand, it is very difficult to calculate the other periods of time because it depends on many factors such as the intelligent software characteristic. Based on the initial design of the proposed system which is illustrated in next chapters, it is expected that the period of time needed for the microcontroller to be in active mode is 10 minutes per day, and 20 minutes in standby mode, and the rest of time in sleeping mode.

$$Totalcapacity = T_{active} \times I_{active} + T_{standby} \times I_{standby} + T_{sleep} \times I_{sleep} \tag{2.4}$$

where $T_{active}$, $T_{standby}$ and $T_{sleep}$ are the total periods of time needed for microcontroller to be in active, standby and sleeping modes, respectively. $I_{active}$, $I_{standby}$ and $I_{sleep}$ are the current needed for microcontroller to be in active, standby and sleeping modes, respectively.

By applying Equation 2.4, the total capacity equals

$(10(\mathrm{md})\times 60(\mathrm{sm})\times 365(\mathrm{dy})\times 15(\mathrm{year})) \times 0.2\mathrm{mA} + (20(\mathrm{md})\times 60(\mathrm{sm})\times 365(\mathrm{dy})\times 15(\mathrm{year}$ $\times\ 0.007\mathrm{mA} + (1410(\mathrm{md}\times 60(\mathrm{sm})\times 365(\mathrm{dy})\times 15(\mathrm{year})) \times 0.0001\mathrm{mA}$

where, m is minute, s second and y year. Total capacity =657000mAs+ 45990mAs +46318.5mAs The total capacity required for the microconroller to work for a cycle of 15 years is 749308.5mAs

The the total capacity required for the proposed system ( the valve, transceiver and microcontroller) to work for a cycle of 15 years is the summation of power needed by the main components of the system and this equals 871966.761mAs. 122576.136

## 2.7 System Analysis and Architecture Design

In software engineering, there are many steps that should be taken before starting to build and implement any software or hardware system. The first step is problem definition. The main object of any system is to solve a specific problem. The second step after defining the problem is the feasability study. This step should lead to evaluate the system and to calculate the cost (*i.e.* the availability of the tools needed) and evaluate the final result. Then the system should be analysed by using specific methods. System analysis include many steps such as determining the functions of the system, the functional requirements, and none functional requirements and divide the system into subsystems to make the design and implementing steps more easy. The last step that should be done before start implementing the system is system design. The main aim of this step is to determine the components of the system and understand the communication methods that are used between the subsystems. The method that should be used to design the system depends on the system type, for example the data base system need specific method and a real time control system like the proposed system also need another specific method [103].

### 2.7.1 System Analysis

In this section, the main requirements that should be provided by the system is determined and illustrated below.

- The user (patient, physician) should be able to open /close the valve wirelessly via transceivers and microcontroller through the internal valve schedule.
- The physician should be able to access the ICP data which is stored in the implanted flash memory.
- The physician should be able to access the internal shunt programme for updating and modifying the internal valve and sensor parameters.
- The system should have the ability to access the intelligent embedded software and request a specific task.
- The internal program should be able to record the valve state and save it in the implantable flash memory.

In addition, the internal software requirements are listed below.

- Receive the input signal from the patient device
- Analyse the received signal and perform the requested action.
- Ability to generate output signal and transfer it to the output port.
- Run and execute the implanted software subroutines in real time such as valve schedule subroutine to control the opening/closing of the valve, ICP sensor subroutine, RTC subroutine, etc.
- Autonomously Communicant with the patient device in real time.

### 2.7.2 System Design

The next step after analysing the system requirements is designing the system and subsystems. The microcontroller systems are used to control a wide range of systems from simple systems to more complex systems. In general, any system has two main parts, a hardware and software. Currently, there are many methods or techniques used to design a software system such as object oriented method, client-server method and real-time software method. In the proposed system, the system can be classified as a real-time control system, thus the best method to be used in designing the proposed system is a real-time software method. "A real-time system is a software system where the correct functioning of the system depends on the results produced by the system and the time at which these results are produced. A soft real-time system is a system whose operation is degraded if results are not produced according to the specified timing requirements. A hard real-time system is a system whose operation is incorrect if results are not produced according to the timing specification" [103].

After determining the functional and non functional software requirements and select the best method for designing the software, the next step is dividing the system into subsystems.

This system is divided into four subsystems for clearer and easier implementation: the valve-microcontroller subsystem,the RF transceiver-microcontroller subsystem, the memory-microcontroller subsystem, and the intelligent software subsystem. These subsystems are explained in Appendix A.

## 2.8 Results and Conclusions

Many factors have been taken into consideration for selecting the implantable microcontroller, transceiver and the battery such as power consumption, size and compatibility with MICS. As a result, MSP430f1611 microcontroller and ZL70101 RF transceiver have been selected. In order to select a suitable battery, the expected power consumption required to fulfil the functions of the implantable system was calculated.

The ZL70101 Application Development Kit (ADK) has been used in this work to make up a complete MICS test and evaluation system based on Zarlink's ZL70101 Implantable Grade RF Transceiver IC. In addition, it is used to test a wakeup operation by using 2.45GHz antenna. This kit consists of two parts: Base Station Module(BSM) (shown in Figures 2.7) and Application Implant Module (AIM) (shown in Figures 2.8).

These are the functional levels of hardware and software for the base station implant applications, respectively. Each part contains ZL70101 RF transceiver, Dual Band Helical Antenna and M430F1611 microcontroller.

The data transfer operation between BSM and AIM through 400MHz antenna has been done through Zarlink graphical user interface (shown in Figures 2.9).

The constant initial valve schedule (shown in Figure 2.10 has been written in C language using IAR software, then uploaded into the M430 microcontroller and tested by using the ZL70101 ADK through the MICS channel.

The components of the proposed shunting system have been selected and the methods of communication between these components have been illustrated. Figure 2.11 shows the design of the proposed shunting system.

An initial time-based valve schedule has been created and tested using IAR embedded workbench and Texas instrument Kit which has M430FG4618 and F2013

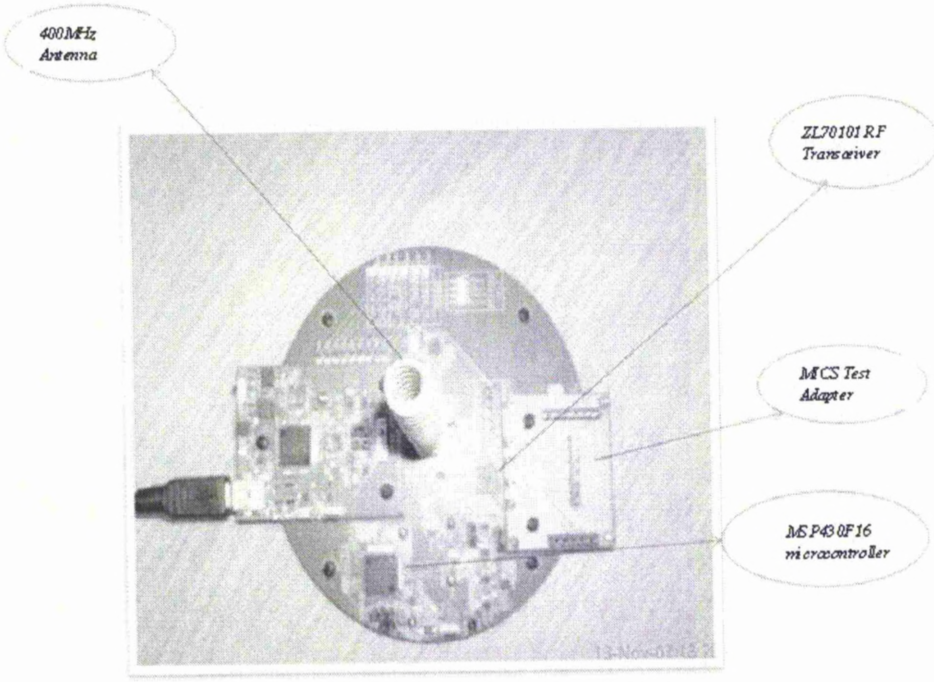



FIGURE 2.7: Base Station Module (BSM).

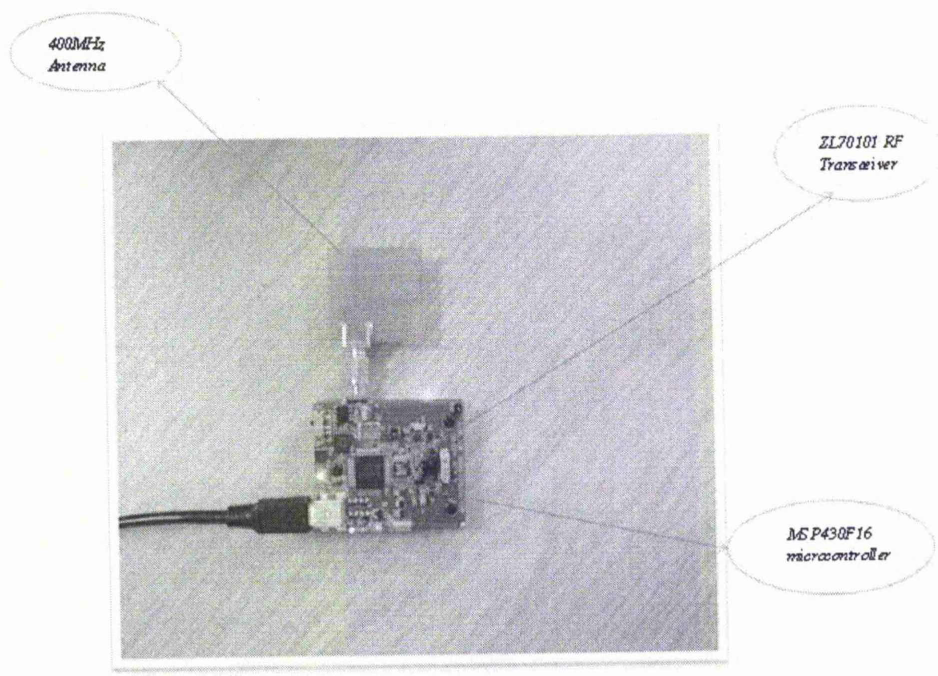



FIGURE 2.8: Application Implant Module (AIM).

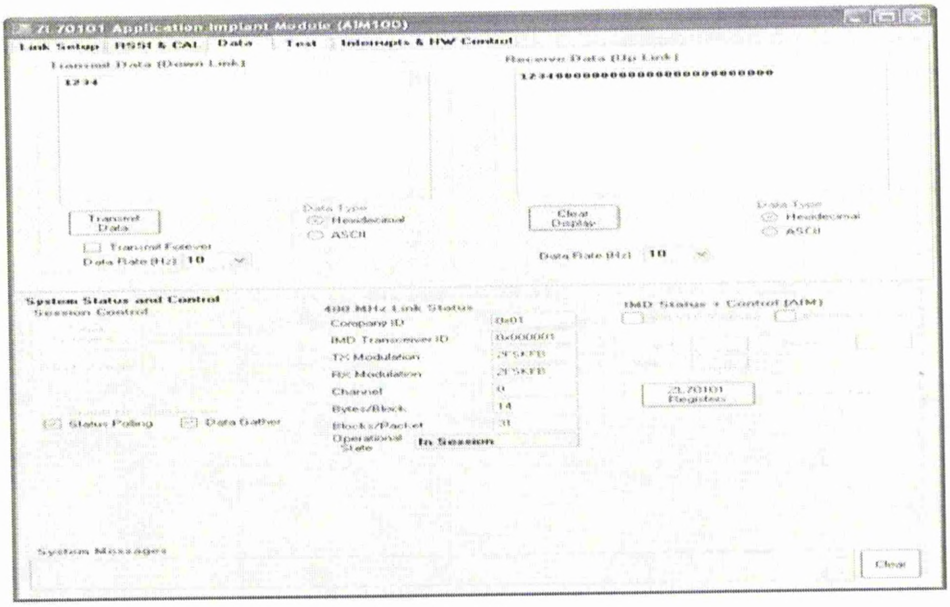


FIGURE 2.9: Zarlink Graphical User Interface.

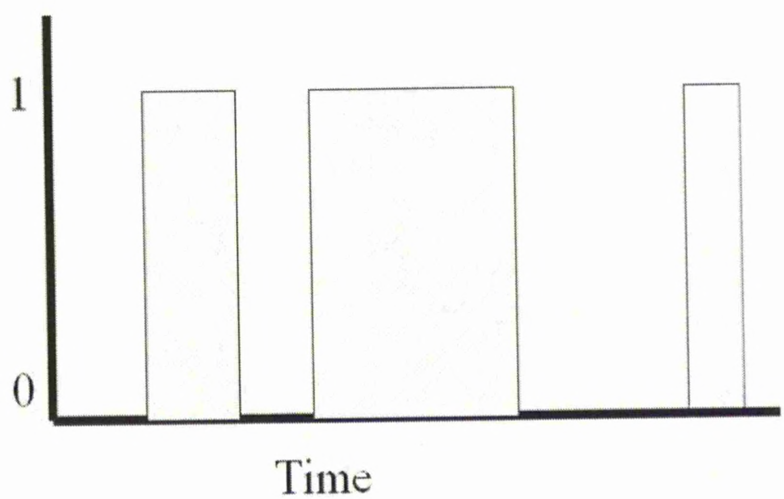



FIGURE 2.10: Constant initial valve program duration time (0 present valve closed and 1 present valve open).

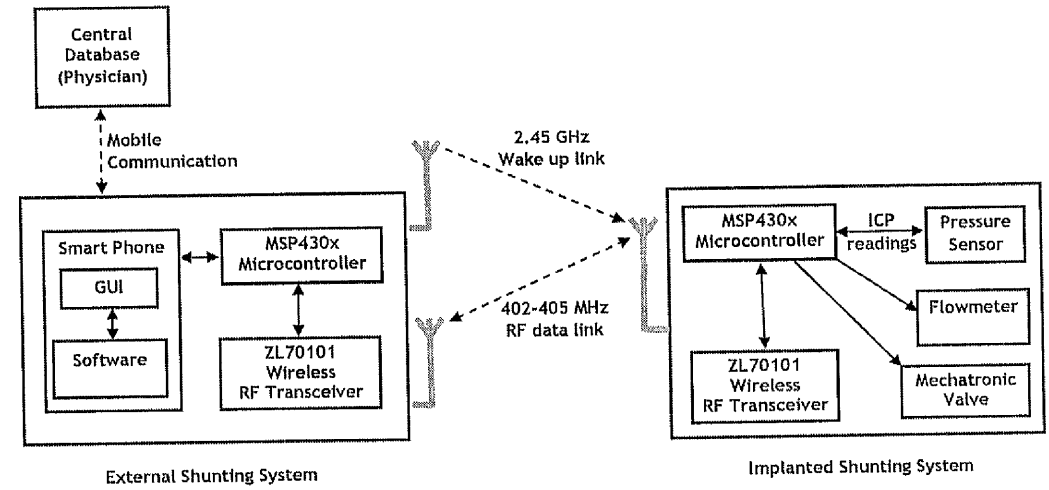



FIGURE 2.11: A design of the proposed shunting system.

microcontrollers.

# Chapter 3

# System Simulation and Design Optimisation[1]

## 3.1 Introduction

The various components of an intelligent implantable shunting system were illustrated and discussed in the previous chapter. In addition, initial system design was proposed for covering most of the system requirements in order to deal with common shunting systems drawbacks. In system engineering, an important step of system life cycle is redesigning the system to optimise the final design before starting implementation.

In this chapter, the final design of the intelligent wireless shunting system for hydrocephalus patients is presented with features that help in reducing or eliminating the problems of current shunts. This shunting system would consist of hard and soft components. The overall system is shown in Figure 3.1. The implanted hardware components would mainly consist of a microcontroller [110], electronic valve [67], ICP sensor [17] and transceiver [122]. This implantable shunting system

[1]Part of this chapter has been published under the title "An Intelligent Implantable Wireless Shunting System for Hydrocephalus Patients", in Proceedings of 13th International Conference on Biomedical Engineering, Suntec, Singapore, pp. 210-215, Dec 2008.

would wirelessly communicate with a hand-held Windows Mobile-based device operated by the patient, or on the patient's behalf by a clinician or guardian. This device would have a graphical user interface and an RF interface to communicate with the user and the implantable shunt, respectively. The main tasks of the embedded software are determined and summarised below. One of the tasks would involve receiving ICP data from the sensor, analysing it and regulating the valve accordingly. Another task would be wirelessly receiving modifications from the physician through the external patient device. Such modification might involve ICP management parameters such as pressure threshold, valve schedule, etc. On the other hand, the implantable shunting system would send a report either on regular basis or upon request to the physician through the external device. Such reports would consist of information that is useful in understanding this particular patient case. On the long run, this might help in achieving better understanding of hydrocephalus thus helping other hydrocephalus patients. The embedded code would handle self testing of the implanted shunt components such as the valve, ICP sensor, microcontroller and transceiver. This task involves mainly detecting any shunt malfunctions such as valve blockage or disconnected catheters. An important task that make the system unique is its ability to deal with any emergency case. In an emergency situation, the implantable shunting system would receive requests either from patient or physician through the external patient device to open/close the valve or collect ICP readings instantaneously, and identify the cause of emergency. As a result of monitoring the shunt components, the implantable system might request help when facing a problem, *e.g.* valve is open, whereas ICP still high which means valve is not opening and closing due to malfunction. The method of connecting the hardware components was illustrated in Chapter 2 as well as the method of communication between the two subsystems (implantable and external). To reach the optimal design, a management shunting software, a data compression method and power consumption protocol are discussed and illustrated in the following section.

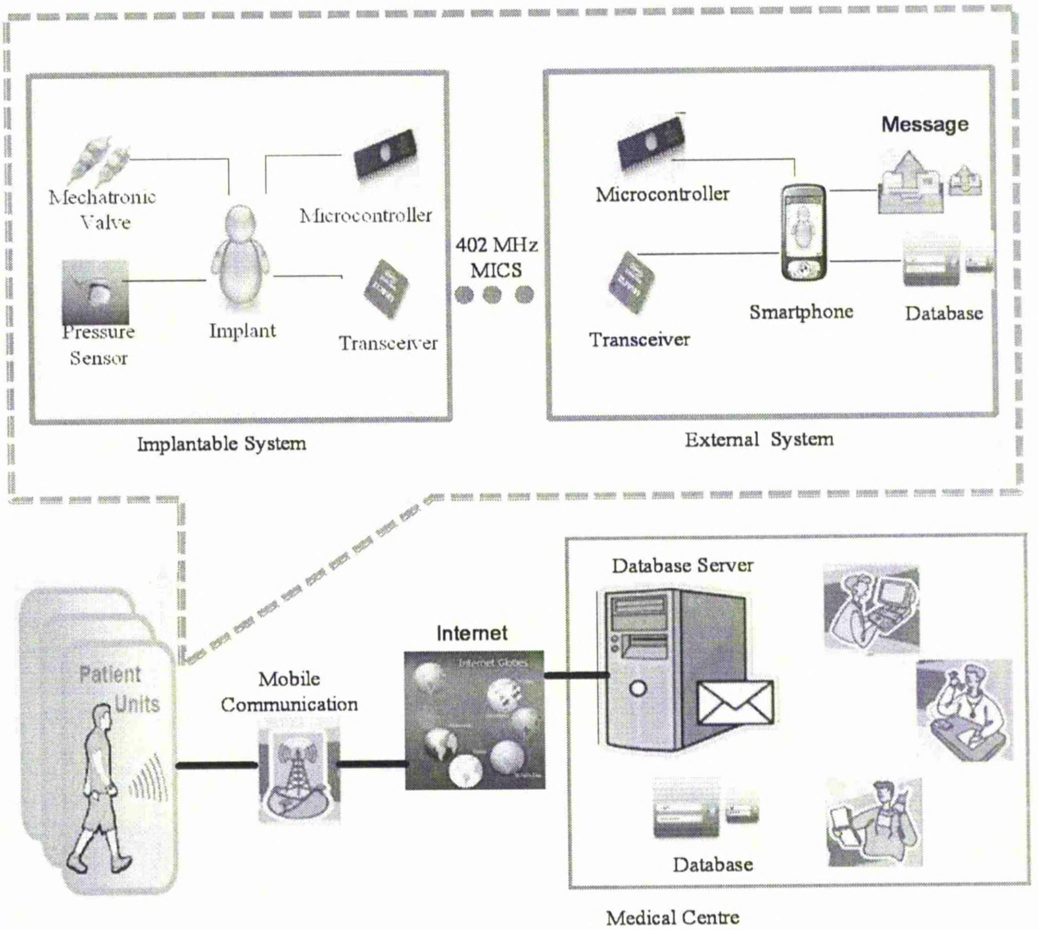



FIGURE 3.1: Mechatronic shunting system

## 3.2 Shunt Management Software

To improve the designing of the embedded software which is responsible for managing the shunting system, four scenarios for designing an embedded code have been investigated and simulated.

Two sources of ICP data were used to evaluate the proposed design of the management software. One is a real data collected at 125Hz sampling rate [14]. The other source is a model of the intracranial hydrodynamics that imitates the behavior of real ICP data for high pressure hydrocephalus patients [71].

The four scenarios are illustrated and explained as follows.

- Fixed-Time Schedule Scenario

  In this scenario, the implanted shunting system would consist of a mechatronic valve, a microcontroller and an RF transceiver. The valve would permit fluid flow only based on a fixed time schedule, *i.e.* valve opens at specific times for certain periods irrespective of ICP. A block diagram of this scenario is shown in Figure 3.2. The implanted valve schedule would be changed remotely by a physician, who determines at what time during the day or night the valve is opened or closed. The problem of such scenario is a mismatch between what is required and what is delivered. This mismatch would cause serious drawbacks *e.g.* overflow, underflow. In addition, it cannot handle real-time patient satisfaction and emergency situations because of the dynamic nature of ICP for the same patient. This scenario has been simulated and tested using real ICP data. Figure 3.3 illustrates the problems of using such approach *i.e.* on ICP overdraining and underdraining.

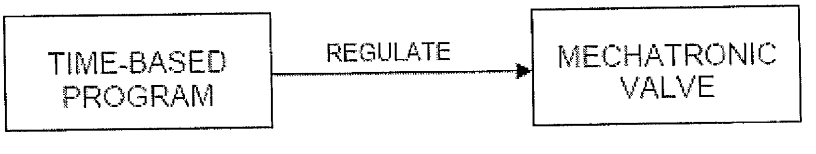



FIGURE 3.2: Block diagram of fixed schedule scenario

- Fixed-Time Schedule Scenario with Pressure Sensor

  This scenario differs from the previous one as it is utilising implanted pressure sensor. The sensor would be used to collect ICP data, and then these

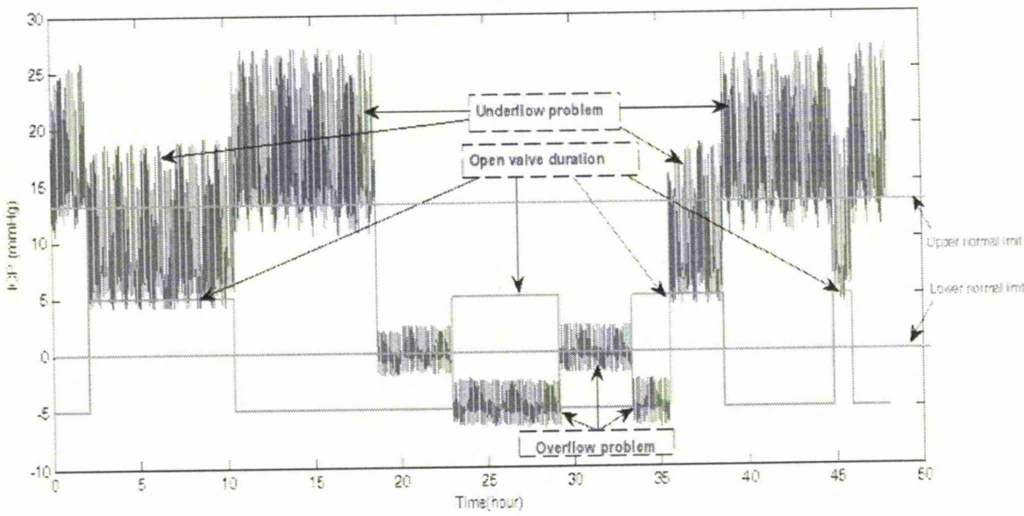



FIGURE 3.3: Fixed schedule problems

readings would be sent wirelessly via the RF transceiver to the external patient device. This data would help the physician in personalising the fixed time schedule and any required modification. Any modified fixed schedule would be uploaded remotely to the implanted shunting system.

- Closed Loop Scenario

  A closed loop shunt would consist of a mechatronic valve, microcontroller and pressure sensor. In this scenario the valve would be instantaneously managed (opened or closed) according to the measured ICP. The collected ICP would be analysed by the embedded software on the implanted microcontroller to decide whether it is an appropriate time to open or close the valve. A block diagram of this scenario is shown in Figure 3.4. Many but not all problems can be solved by using such scenario e.g. overflow, underflow. Figure 3.5 illustrates the resulted ICP waveform for closed loop shunting system. Thus the collected ICP would be utilised only within implanted shunting system. Such data would not reach the physician since there is no need for sending it outside the patient's body. The limitation of using such scenario are presented by power consumption problem and working life of the implantable ICP sensor. By applying such scenario, the implantable components have to be set in active mode all the time to deal with the requirement process, *i.e.* collect ICP data, analyse it and take a decision to open or close the valve. In addition, one of the main challenges of using the implantable sensor for long time monitoring is usage life. In closed loop scenario, the ICP sensor will collect ICP data in real time and this will increase the risk of fault in such sensor.It is noticed that the closed loop scenario is good for a patient but not good for the equipments.

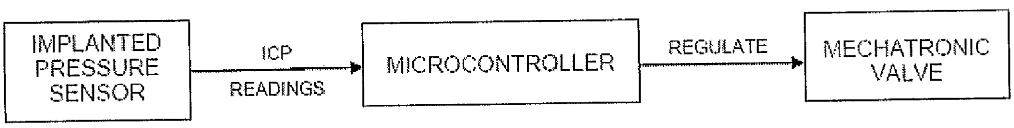



FIGURE 3.4: Block diagram of closed loop scenario

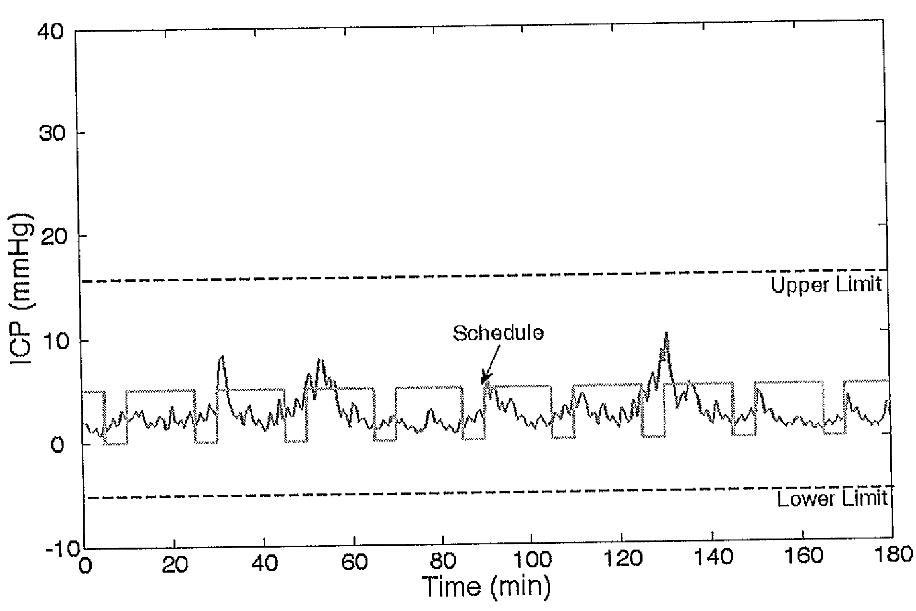



FIGURE 3.5: The resulted ICP waveform for closed loop shunting

- Dynamic Shunting System Scenario

In this scenario, the implanted shunting system includes a mechatronic valve, microcontroller, RF transceiver, ICP sensor, flowmeter and smart software. A dynamic instead of fixed valve schedule would be used in such scenario. A block diagram of this scenario is shown in Figure 3.6. Various sensory inputs would be used in this scenario to modify valve schedule, *i.e.* medical practitioner, ICP readings, patient feedback. This schedule would be modified wirelessly from the external device based on the results of analysing the received ICP data and parameters which will be daily send from the implantable shunt through RF. Figure 3.7 illustrates the resulted ICP waveform and flow measurements for dynamic shunting system scenario

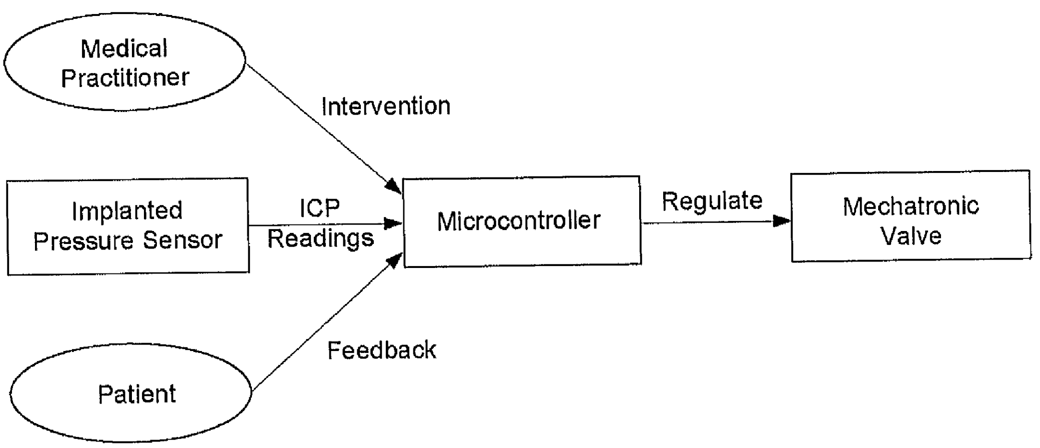



FIGURE 3.6: Block diagram of dynamic shunting scenario

It is obvious that the drawback of previous shunts can be eliminated by using this scenario. Such shunting system would perform the following tasks:

- ICP and flow measurement analysis: The ICP readings and valve flow measurements would be analysed to figure out some important parameters such as ICP waveform components and mean ICP. These parameters would be useful in autonomously modifying the valve schedule internally (discussed in more detail in Chapter 5).

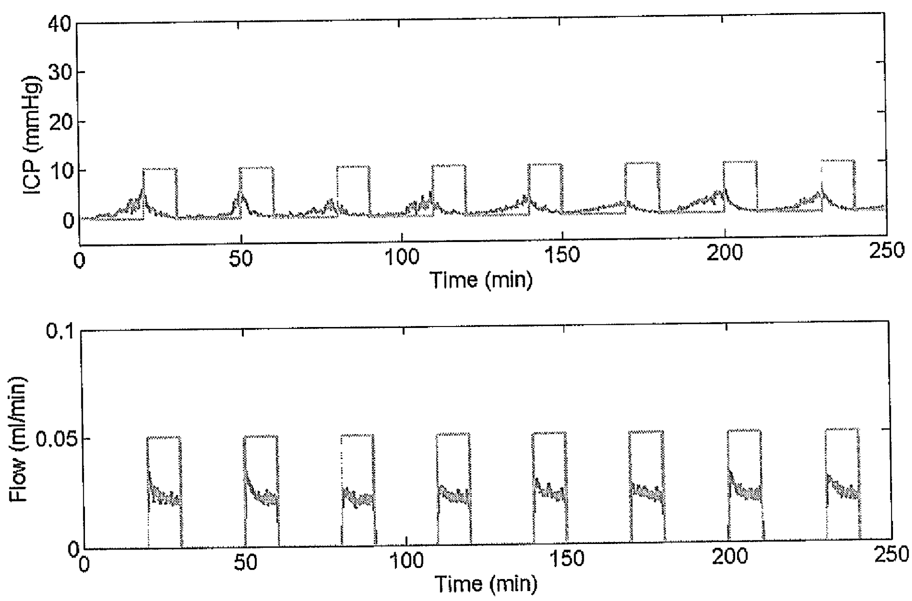


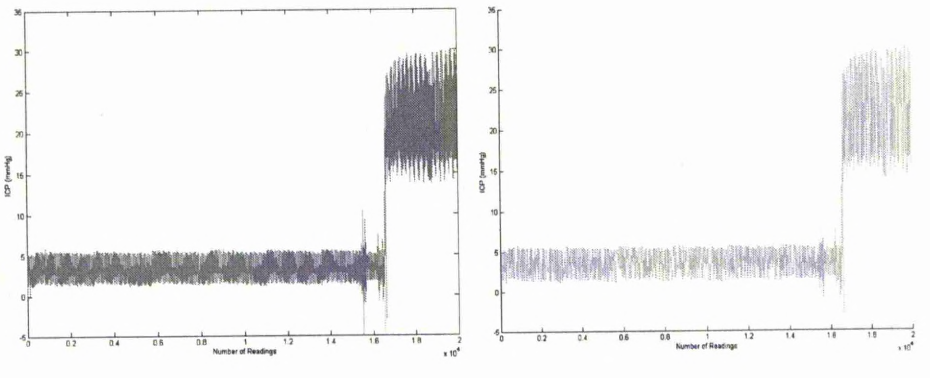

FIGURE 3.7: The resulted ICP waveform and flow measurement for dynamic shunting system

- Self testing: This task involves testing all implanted shunt components. For example, ICP readings and valve flow measurements collected when valve is open would be analysed and parameters are calculated to help in detecting shunt malfunctions such as shunt blockage or disconnected catheter. Also this task would work on checking the functioning of other implanted components such as ICP sensor.

- Emergency call: This task is responsible for all emergency cases that might happen during shunt operation. For example, it would send a signal to inform the external device when shunt malfunctions are detected. On the other hand, it will handle any emergency signals received from the physician through the external device to open/close the valve or to request ICP/flow readings. Also patient feedback as explained in Chapter 7) would be collected and anlysed in order to autonomously modify the valve schedule.

- Schedule modifying: The implantable ICP sensor and the smart software would cooperate in monitoring and determining vital parameters that would help in modifying and optimising the valve schedule.
- Report generating: This task involves generating a report consisting of ICP waveform components, valve status, real ICP readings and their corresponding time, mean ICP and self shunt testing results. This report would be stored in the implanted memory and a copy of this report would be sent remotely to the physician through the external device regularly or upon request. Thus, such report would be useful tool for the physician to monitor and decide any modification on the valve schedule. Also, it would be helpful in understanding hydrocephalus in general.
- ICP compression: A peak detection algorithm has been designed and tested by the author to overcome the problem of the implantable memory size limitation. Matlab code is used to store the peak components and ignore the other components based on comparing between these components values. In case of the current value is bigger than the previous value and at the same time is smaller than the next value, that mean it is a peak value and it will save as apeak. By using this algorithm, only the peaks (upper, lower) of the ICP waveform would be stored. It was noticed that the output waveform of such algorithm give a good estimation of the original waveform. By applying this algorithm, the size of stored data was reduced by more than 93%. Figure 3.8 shows a sample of ICP data before and after compression, where the size of this sample was 20000 readings before compression and it was reduced due to compression into 1246 readings without any effect on the shape

of such signals as well as the values of the derived ICP parameters *e.g.* mean ICP.



(a) (b)

FIGURE 3.8: ICP traces (a) before and (b) after applying the Peak detection algorithm

- Wireless updating: A wireless method was investigated and tested to enable the external device wirelessly modifying different implanted parameters such as valve schedule and ICP thresholds values. Such method rarely mentioned in literature especially for implanted micro-controller. A self learning packet technique has been used in this method to access the implanted memory address of each parameter thatis needed to be modified. This packet is made up of packet length, patient identification, packet identification and the modified parameters values with their addresses. The packet is shown in Figure 3.10.
- Power consumption algorithm: The power consumption algorithm has been integrated with shunt management software and tested to minimise power consumption needed for the implanted shunt. Thee implantable microcontroller and RF transceiver are kept sleeping mode to reduce the power consumption. A wake up signal from external device

would be used to wake up these components when it is needed. Such protocol is explained in details in the following section.

Most of these tasks are coded using assembly and C languages. MSP430 development kits, shown in Figure 3.10, was used to test these tasks.

## 3.3 Power Consumption Algorithm

Biomedical implants require a clean and medically safe source of energy to perform their operations. Early implants such as pacemakers sourced their power from small lithium ion batteries. While this solution allows for the operation of the implantable device without a wire connecting the internal and external circuity, limited battery life causes the impracticality due to the needed of replacing the battery every short time, health risks and expense of operating on patients for the mere purpose of replacing the battery. To the best knowledge of the author, there is no novel methods in recharging the implanted batteries from external source. Some researchers have done a theoretical research in this area and it was based on wirelessly recharge the implanted battery via RF transceivers [104]. Up to this moment, the implanted battery needs to be replaced when it loses its capacity. This has motivated the author to find a suitable method to make the implantable battery life as long as possible.

Based on the previous calculations of the power needed for the proposed implantable shunting system, it is essential to find out a method to control the state of the implantable components (MIC and RF). In addition, it should control the transfer operation between different power consumption modes (sleeping, standby and active modes).

The current methods used to activate the microcontroller is based on external interrupt signal that is generated from other devices *i.e.* sensor, video camera.

Such methods are impractical to be used in the implantable devices due to the difficulty of interfacing such devices with human body. On the other hand, one of the most important features of the implanted battery is its size. The size of the implantable battery should be as small as possible to be implanted inside the human body. The limitation of the battery size directly affects the maximum capacity of such battery. In normal case, the maximum capacity of any implantable battery can supply the implantable device, i.e. proposed shunting system, not more than two weeks when the components of such system stay in active mode all the time. Therefor, a surgery is frequently needed to recharge or replace the implanted power supply (the battery) which cause suffering for the patient and increase the risk on his/her life.

Thus to avoid frequent surgeries, an autonomous wake up method for the implanted microcontroller is required. One of the most important features of the selected microcontroller is its ability to work in three different modes (active, sleep and standby). In addition, it has two internal timers that are supplied from other clock sources.

A power consumption algorithm is proposed where it is designed based on using such internal timers to give a wake up signal to the microcontroller when it is needed. A real time clock has been used in this algorithm to decide when the microcontroller needs to wake up to do a specific task or when it should stay in sleeping mode. For example, the microcontroller can be waked up every one minute to contact the embedded shunting software and check if there is a task waiting to be executed then executing it or otherwise switch into sleeping mode.The tasks could be opening/closing the valve, collecting ICP or flow, or responding to external signal. This microcontroller cycle would be repeated in real time. The proposed algorithm is shown in Figure 3.9.

Initialize Microcontroller setting

Initialize and start RTC software (hh:mm:ss)

Set microcontroller in sleeping mode

Every minute:

Generate internal wake up signal from timer1

Wake up the microcontroller

Check the required tasks:

- Run valve schedule subroutine
  - If time to open /close the valve then send to open/close
  - Else got to next step
- Run ICP sensor subroutine
  - If time to start collect ICP readings then start
  - Else got to next step
- Run flowmetre subroutine
  - If time to start measure valve flow then send to start
  - Else go to next step
- Send/receive data
  - If time to send/receive data then wake up transceiver and start
  - If there any external emergency signal or external request then start to execute

Set microcontroller in sleeping mode

Repeat in real time

End

FIGURE 3.9: The proposed power consumption algorithm.

This algorithm has been designed, implemented in C code and tested. Applying such algorithm has reduced the power needed for the components of the implanted shunt by more than 90%. MSP430 development kits, shown in Figure 3.10, are used to test and evaluate this algorithm.

## 3.4 Results and Conclusions

The result of simulating the fixed-time schedule scenario is presented in Figure 3.3. It can be noticed that there is a mismatch between what is required and what is delivered by applying such scenario. The simulation result of closed loop scenario is shown in Figure 3.5. It illustrates the efficacy of the closed loop scenario in keeping the ICP within normal range. On the other hand, other current shunt problems such as difficulty of shunt malfunctions detection, is not solved in closed loop scenario. These problems could be solved by using a dynamic shunting system having a degree of "intelligence". One of the most difficult challenges of using an implantable microcontroller in medical applications is how to access, modify and replace the embedded program. A method for wireless updating the implanted memory contents was investigated to deal with such problem and it will explained in details in Chapter 4. A peak detection algorithm of ICP waveform is utilised by which the size of ICP data is reduced by 93%, thus overcoming the implantable memory size limitation. The previous tasks of the proposed dynamic shunting system, the power consumption algorithm and the peak detection algorithm have been tested and evaluated using transceiver models which are shown in Figure 3.10. A promising result was concluded and most proposed goals were achieved by applying dynamic shunting system, power consumption algorithm and peak detection algorithm. The simulation results show that most of current shunting system drawbacks could be solved by using mechatronic valve with the proposed dynamic shunting system.

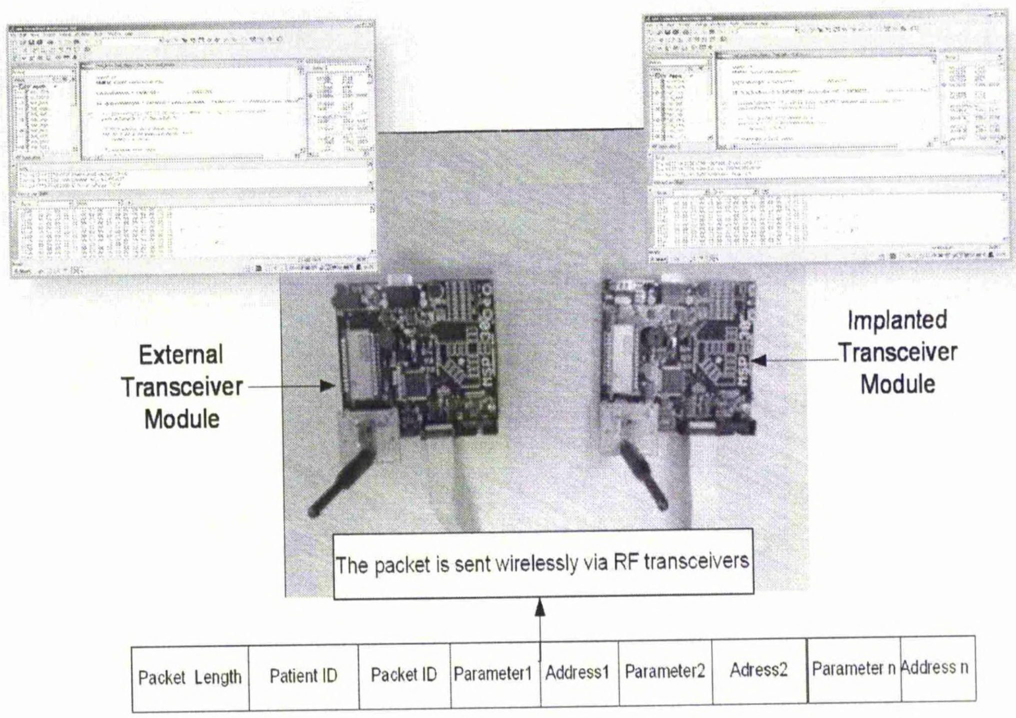



FIGURE 3.10: A prototype of dynamic shunting system

# Chapter 4

# A Bidirectional Wireless Management Protocol for a Mechatronic Hydrocephalus Shunt[2]

## 4.1 Introduction

In 2005, Miethke [67] was awarded patent for hydrocephalus valve with an electric actuating system. This valve would allow improved adaptation to the situation existing in a patient in case of a hydrocephalus valve. Also the mechatronic valve would add a new option for hydrocephalus shunts that is aiming to treat hydrocephalus not only controlling it. This could be achieved by establishing a controlled arrest of the shunt and improving hydrocephalus treatment.

The principle of controlling such valve is by using a time based schedule. Such schedule would incur many disadvantages e.g. overdrainage/underdrainage, if its selection is arbitrary. In order to optimise the usefulness of such valve, a need

[2]Part of this chapter has been published under the title "A Bidirectional Wireless Management Protocol for Mechatronic Shunting System", in 4th International Conference on Broadband Communication, Information Technology and Biomedical Applications, Wroclaw, Jul 2009.

for method and approach to manage and control the valve is essential to manage hydrocephalus.

To eliminate previous disadvantages, a design of wireless mechatronic shunting system was proposed in Chapters 2 and 3. The main tasks of this system were discussed and illustrated. A bidirectional management protocol is needed to achieve these tasks such as reprogram, modify or replace the time based schedule of this valve remotely.

This bidirectional protocol has been proposed and developed for wirelessly managing the mechatronic shunting system. This protocol has three main contributions. First, remotely reprogram the implanted mechatronic shunt by replacing the values of vital implant parameters such as valve schedules, intracranial pressure threshold values and pressure sensor settings. Second, the usefulness of this approach is demonstrated using real time sleeping schedule for the microcontroller to reduce the power needed. Third, a problem associated with memory size limitations has been addressed by using an embedded software to derive the required values of needed parameters when required without saving these values. These parameters explained later in more details.

In this chapter, several wireless data transmission tasks of this protocol are discussed and implemented. The framework of the system is described, and the functions of the main system are illustrated. The shunt management protocol is implemented and tested to demonstrate practicality,reliability and flexibility.

## 4.2 Dynamic Shunting System

An intelligent implantable wireless shunting system for hydrocephalus patients with features that help in reducing or eliminating the problems with current shunts was proposed in Chapter 3 [73]. Such system would provide an inductively powered sensing and transmitting unit which is completely implanted with no wires or tubes penetrating the skin. An external unit outside the body would receive signals from the implanted unit. The received signals may be recorded, displayed, or analysed, or all of these manifestations of the signals may be produced simultaneously.

The main goals of the mechatronic shunting system are to improve the management and treatment of hydrocephalus that should lead to improve the quality of life for hydrocephalus patients.

One of the main functions of the proposed system is enabling the patient or on the patient's behalf to control the state of the internal valve, via the external patient device, as well as enabling the patient to query the internal pressure transducer and view logs/plots of ICP and valve activity over extended periods. Another function would be allowing a technician to wirelessly reprogram the implanted microcontroller via the external patient device and reconfigure the valve schedule, ICP sensor schedule and other important implanted parameters. On the other hand, mobile health technology (M-health) would be used by using remote diagnosis, distance mobile nursing and daily data collection. In our proposed system, a patient's device would use the Medical Implant Communications Service(MICS), which operates in 402 to 405 MHz band and allows for much higher bandwidth (250 Kbps) to collect ICP data from the implanted unit then forward this data dynamically to patient's account in central database in the hospital where nurses or physicians can monitor continually or check the medical data at regular times as needed. In addition, a software inside the implanted system would be used to intelligently generate and derive valve schedule parameters(open and closed duration). A schedule for collecting ICP data (sensor schedule) would also be derived.

Minimising power consumption is essential for any implantable device. A Software-based real time clock (RTC), which uses the built-in capabilities of a microcontroller to keep track of time in a "real mode", is used with power consumption algorithm to minimise the power that is consumed by the implantable unit [4]. To achieve the previous tasks, a wireless shunting protocol is needed and it is proposed in this chapter as below.

## 4.3 Bidirectional Wireless Management

An Intelligent shunting protocol will enable physicians monitoring of a variety environments for hydrocephalus patients. The researcher looks at a novel communication method which has significant impact on replacing the current valves with mechatronic valves. The wireless shunting monitoring idea is to wirelessly gather ICP readings which are collected from the implanted sensor and environmental data coming from the implanted microcontroller through RF, then Intelligent presentation of patient data for diagnosis. On the other hand, send all implanted system parameters required to make a system work such as update or replace current used valve schedule and more other parameters. Furthermore, It enables the physicians remotely open or close the valve and stop or start the ICP sensor when it is needed. A management shunting protocol has been developed to perform these tasks. Several tasks of this protocol are discussed and analysed below in details

### 4.3.1 Valve and ICP Sensor Schedule Updating

The mechatronic valve is controlled and regulated by a time based schedule. This schedule shown in Figure 4.1 equipped for 24 hours. For each hour two parameters are identified; open duration (d) to illustrate the opening time of the valve and period(p) to illustrate the length of opening and closing time. The valve should open one or more time per hour on specific times for fixed length. This schedule is stored in the implanted RAM. After each wake up operation, the implanted software reads this schedule, derives the opening and closing times for each hour according to the Equations 4.1-4.3, and then compares it with a real time clock. Based on this, a control signal is sent to open or close the valve.

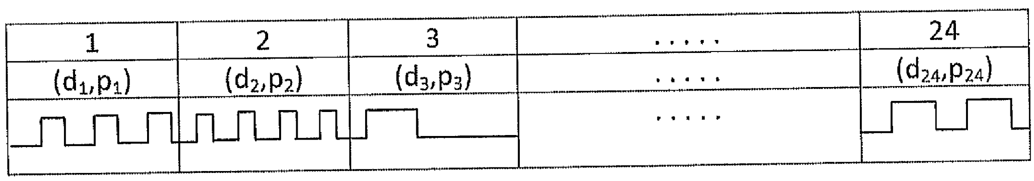



FIGURE 4.1: Time based valve schedule.

The implanted software would also derive the ICP sensor schedule from the valve schedule according to the Equations 4.4-4.6. Where the sensor schedule identifies the times at which the sensor should collect ICP data. To monitor hydrocephalus and the shunting system and diagnose its faults, the sensor would collect ICP data at the beginning and ending of each open valve duration. In addition, it will collect data at the middle of each closed period to monitor hydrocephalus when valve set in closed period.

$$NPR = \frac{60}{period(p)} \tag{4.1}$$

where $NPR$ is the number of times the valve is opened per hour, period is the length of opening and closing time.

$$T_o = (I.period(p)) - duration(d) \tag{4.2}$$

where $T_o$ is the time at which the valve is opened in minutes, and $I$ is counter starts from 1 and ends with $NPR$.

$$T_c = (I.period(p)) \tag{4.3}$$

where $T_c$ is the time at which the valve is closed in minutes.

$$Ts_o = (I.period(p)) - duration(d) \tag{4.4}$$

where $Ts_o$ is the time at which data is collected at the beginning of each open duration.

$$Ts_{c1} = (I.period(p)) \tag{4.5}$$

where $Ts_{c1}$ is the time at which data is collected at the ending of each open duration.

$$Ts_{c2} = (I.period(p)) + \frac{period(p) - duration(d)}{2} \tag{4.6}$$

where $Ts_{c2}$ is the time at which data is collected in the middle of each closed duration.

One of the novelty aspects of the proposed shunting system is its ability to wirelessly modify or replace an existing implanted valve schedule via the external system. A packet as shown in Figure 4.2 was wirelessly sent to the implanted system with new parameters' values to replace the existing valve schedule. For example, to modify the opening time for specific hour, the packet should include hour index, open period and open duration for that hour. When the packet is received, it will be decoded to find out the requested task, then the current schedule would be modified or replaced by new one. Figure 4.3 illustrates this operation.

| Packet Length | Patient ID | Packet ID | Number of slots(1..m) | Hour index1 | d1 | p1 | ----- | Hour index$_m$ | $d_m$ | $p_m$ |
|---|---|---|---|---|---|---|---|---|---|---|

FIGURE 4.2: Packet format of valve schedule updating.

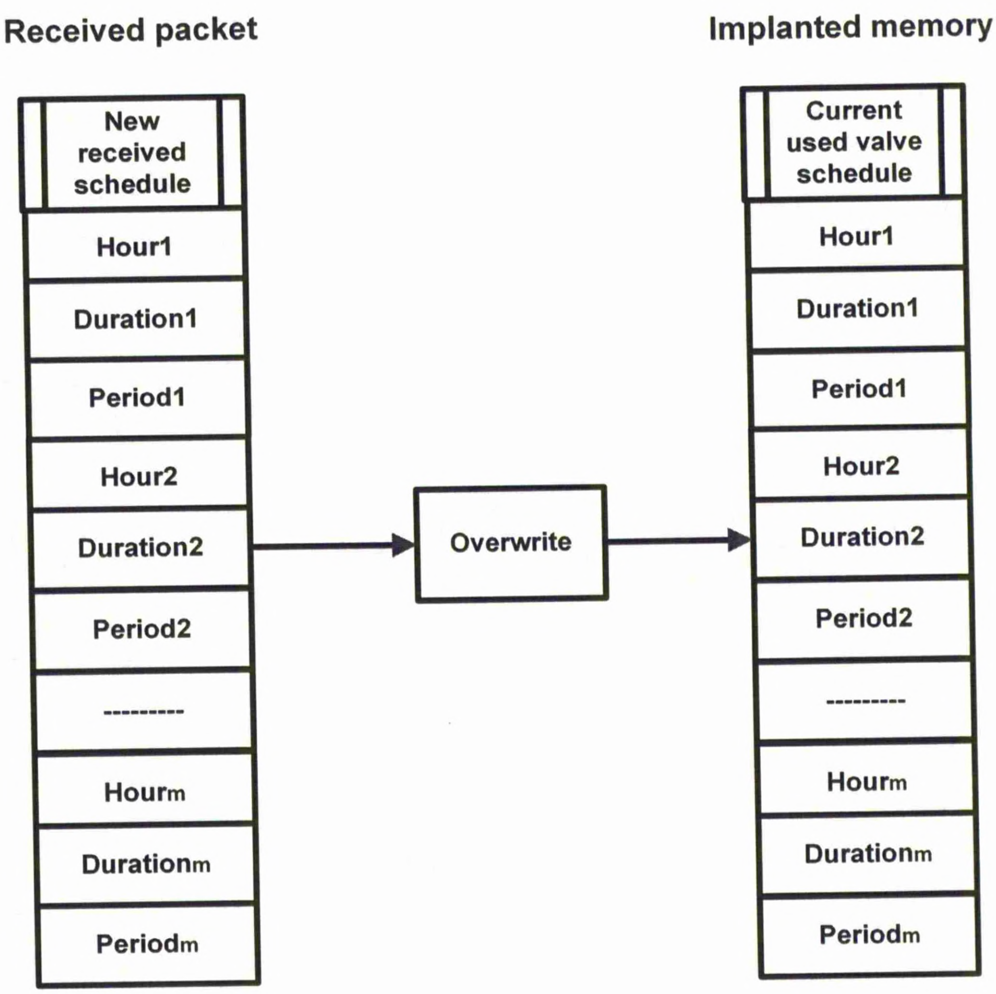



FIGURE 4.3: Schedule updating block diagram.

### 4.3.2 Valve Status is Wirelessly Controlled

To add more flexibility, this system would enable manual intervention by physician to control and regulate the valve wirelessly. The intervention is wirelessly sent through the external device to the implanted system to open or close the valve for a specific time. The implantable system would receive, encode and analyse this packet. Based on the packet identification (packet id) which is used to present the required task, the control signal would be sent to the valve, *i.e.* if packet identification equals 1 then open the valve, if packet identification equals 2 then close the valve or if packet identification equals 3 then follow the routine implanted valve schedule to regulate the valve. At the end of the specified open/closed time, the implanted system will switch to follow the routine schedule. A packet format of this task is shown in Figure 4.4.

| | | | | | |
|---|---|---|---|---|---|
| Packet Length | Patient ID | Packet ID | Valve status | Duration | Schedule flag |

FIGURE 4.4: Packet format for wirelessly valve controlling.

### 4.3.3 Implanted Parameters are Wirelessly Modified

The modification operation performed by the proposed protocol does not stand only at modifying the valve schedule but it also extends to modify any other implantable parameters, *e.g.* ICP thresholds, sensor sampling frequency, that might need to be changed after the shunt being implanted. The need to make the parameters' value dynamic, not fixed, rises due to the dynamic nature of the intracranial hydrodynamics that change with time. For example, in a patient older than 55 the resistance to CSF outflow increases $0.2mmHg/(ml/min)$ per year [28]. The packet format is shown in Figure 4.5.

| | | | | | | | |
|---|---|---|---|---|---|---|---|
| Packet Length | Patient ID | Packet ID | Parameter p1 | Parameter p2 | Parameter p3 | -------- | Parameter pn |

FIGURE 4.5: Packet format for parameters modification.

### 4.3.4 Intracranial Pressure Monitoring

Measurements of ICP improve the outcome in patients with hydrocephalus. Because ICP measurement is of clinical importance, the proposed shunting system posses a pressure sensor that provide ICP readings noninvasively with no need for hospitalisation and not affecting his morbidity thus reducing patients' suffer, improving the quality of treatment and gaining a valuable resource of ICP data for the patient while living his live. The embedded software would determine some important parameters for this ICP data such as mean ICP, valve status when these readings were collected and the time of collecting these readings. One of drawbacks of current ICP monitoring is the missing of some important parameters when such ICP data collected such as valve status when this data collected. It is attempted to solve this problem in this ICP monitoring approach by recording the valve status, the time and mean ICP for each sample. This important clinical data is stored in the implanted memory for 24 hours. The external system will automatically backup this data every day. This data is utilised by the external system to manage and treat of hydrocephalus and manage the shunting system itself. An example of this, modifying the implanted valve schedule according to the collected data. Furthermore, it will be helpful in treating other patients, in understanding hydrocephalus and possibly published.

This protocol would generate two types of clinical reports. One of the reports would have ICP readings and valve flow measurements for last collected sample. The external system has ability to request this report or request a sample of ICP readings and flow measurements when they are needed. Such sample would be included in this report and wirelessly send it back to the external system. The other report includes the derived ICP and flow parameters that are calculated for each sample. These samples were collected based on ICP sensor and flowmeter schedules which were derived based on valve schedule, *i.e.* the sensor and flowmeter used to collect six seconds window size at very short time before the valve is opening and closing and in the middle of valve closed period. The implantable software derived a selected parameters for each sample such as mean ICP, mean absolute deviation, mean valve flow, valve status when the sample collected and sample collecting time. The derived parameters for 24 hours schedule were stored in RAM. The external system automatically request this daily report or when it is needed. Figure 4.6 presents the packets format for requesting these two reports.

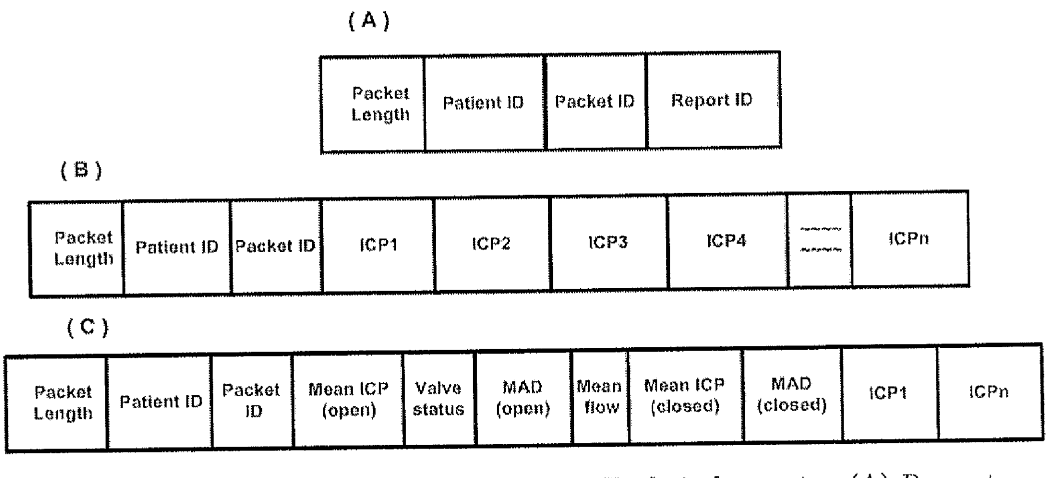



FIGURE 4.6: Packet formats for different ICP clinical reports. (A) Request report, (B) ICP data, and (C) ICP parameters.

### 4.3.5 Closed Loop Option Activating

A closed loop shunt would consist of a mechatronic valve, microcontroller and pressure sensor. In this scenario the valve would be instantaneously managed (opened or closed) according to the measured ICP. Where the collected ICP would be analysed by the embedded software (located in the microcontroller) to decide whether it is an appropriate time to open or close the valve. The proposed shunting system is set to work as a closed loop system in cases of emergency to save the patient's life. The external software system or the physician has the ability to wirelessly swap the mode of the implanted system between dynamic shunting and closed loop shunting systems. The implanted shunting system can work as a closed loop system for specific time, and then return back to previous mode. This scenario is implemented by sending a packet from external system. Upon receiving this packet, the embedded software decodes and analyses it, and set the implanted system to work as a closed loop. As a consequence, the ICP sensor starts collecting data, the software calculates mean ICP and compares it with maximum and minimum ICP threshold values to make a decision whether to open or close the valve. Upon the specified time for closed loop is elapsed, the shunting system returns to work as a dynamic shunting system. The valve status and ICP readings during operating as a closed loop are stored in implanted memory and sent to the external system to be utilised as a resource in understanding patient's case and improve the efficiency of the shunting system. A closed loop scenario is presented in Figure 4.7.

### 4.3.6 Emergency Cases

One of the benefits of using a mechatronic shunting system is the ability of autonomously monitoring the hydrocephalus patient in real time in any emergency case or system malfunctions. The emergency arises when there is a sudden rise or drift due to different reasons such as shunt malfunctions. This protocol is designed to deal with such emergency. An emergency request is received either from the implanted system or from the physician or patient/in the patient behalf.

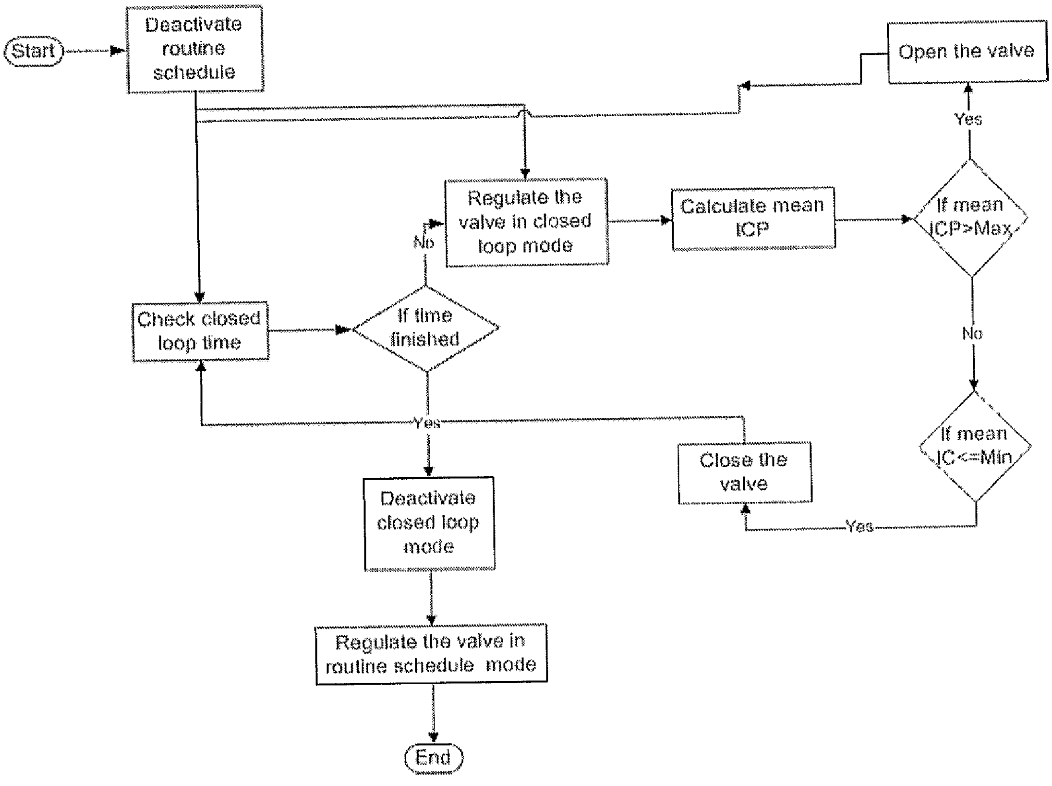



FIGURE 4.7: Closed loop scenario.

Three thresholds of mean ICP were selected for emergency case and based on these thresholds, the implanted system would select a risk factor (RF). The risk factor is a number that would be selected by the embedded software based on the degree of ICP rise/drift and it will be used externally to decide the degree of emergency request. In this work, the degree of emergency is divide into three categories: low risk emergency accompanied with RF =1, medium risk emergency accompanied with RF=2 and high risk emergency accompanied with RF=3.

This operation starts calculating the hourly mean ICP for the collected samples and classifying the calculated values based on the stored emergency thresholds. The emergency request would by wirelessly send with risk factor to external system. Upon receiving the emergency request, the external system would deal with such case as follow, (1) the external module receive the request, analyse it and make a decision based on RF value, (2) The decision will be guided by the following criteria: in case of RF equals 1, shunt will continuous to work as normal but the external will request a sample of ICP readings and flow measurements to be analysed to check the accuracy of the request. in case of RF equals 2, the external system will directly activate the closed loop option by sending a packet to implanted module as explained in previous section. in case of RF equals 3, the valve would be opened or close based on case of either rising or drift of ICP. (3) the external system would request ICP emergency report which include ICP readings, flow measurements and valve status after waiting a short time, (4) the external system would analyse the received report and check the status of ICP, (5) and finally the external system would take a suitable final action based on the value of ICP *i.e.* deactivate closed loop option, open the valve, close the valve, contact the physician or inform patient by a message that the shunt is work normally. The proposed emergency scenario is presented in Figure 4.8.

### 4.3.7 Interference Prevention

To improve patient safety, this protocol is designed to prevent any interference problem or communication with an unauthenticated device. The scenario of this task shown in Figure 4.9 where patient identification number is added as a part of the header of all sending packets. The patient identification is then verified by the receiver to avoid any interference or any unauthorised communication. In case of any mismatch between the stored and received patient id, the communication will be banded and a message will be send informing of occurrence of such problem. On the other hand and if the received packet identify itself correctly, the communication would start between two shunting subsystems to perform the required task.

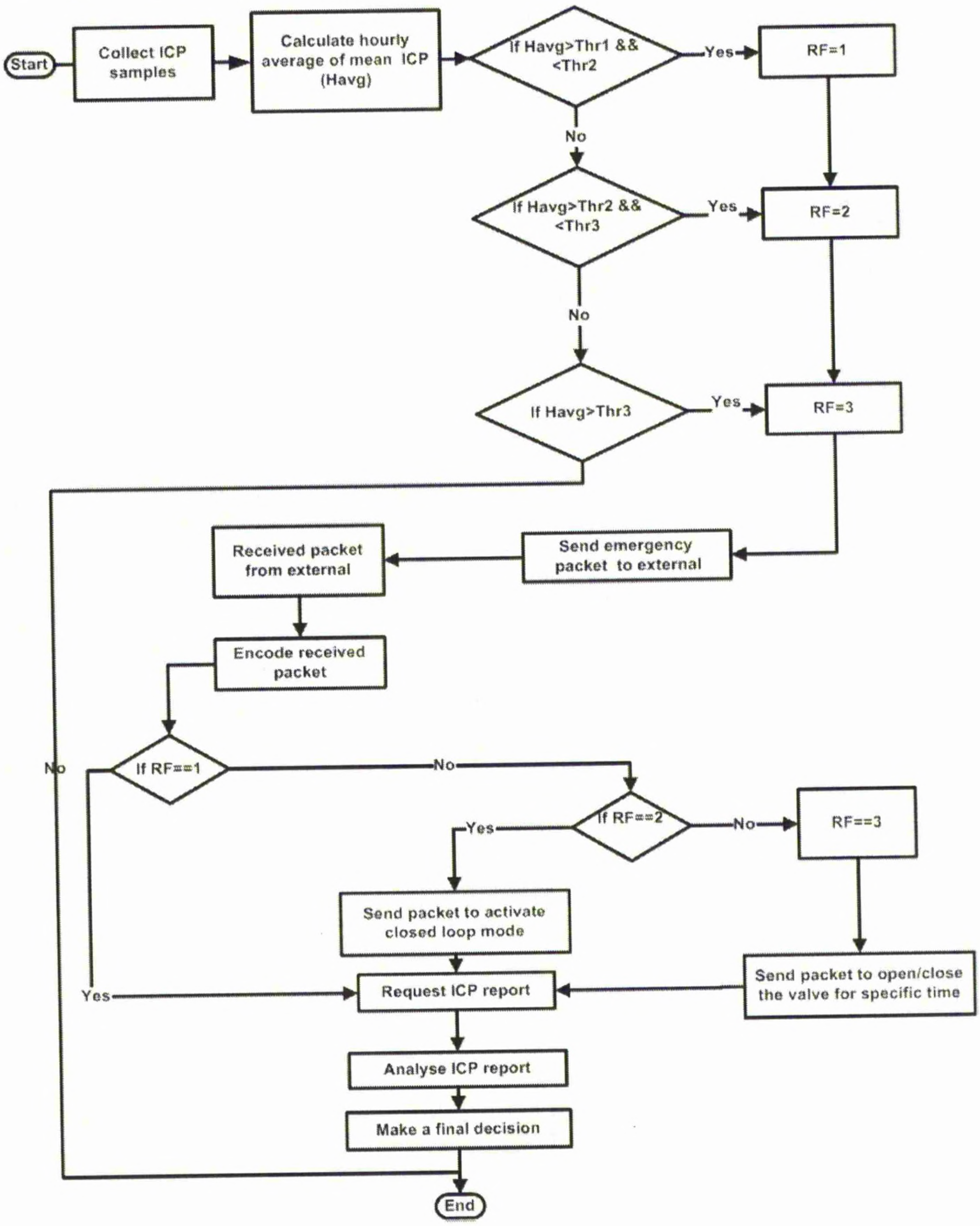



FIGURE 4.8: Emergency scenario.

## 4.4 Experimental Results and Discussion

All management shunting protocol functions including power consumption are written in C code and compiled by IAR Workbench. MSP430 development kits

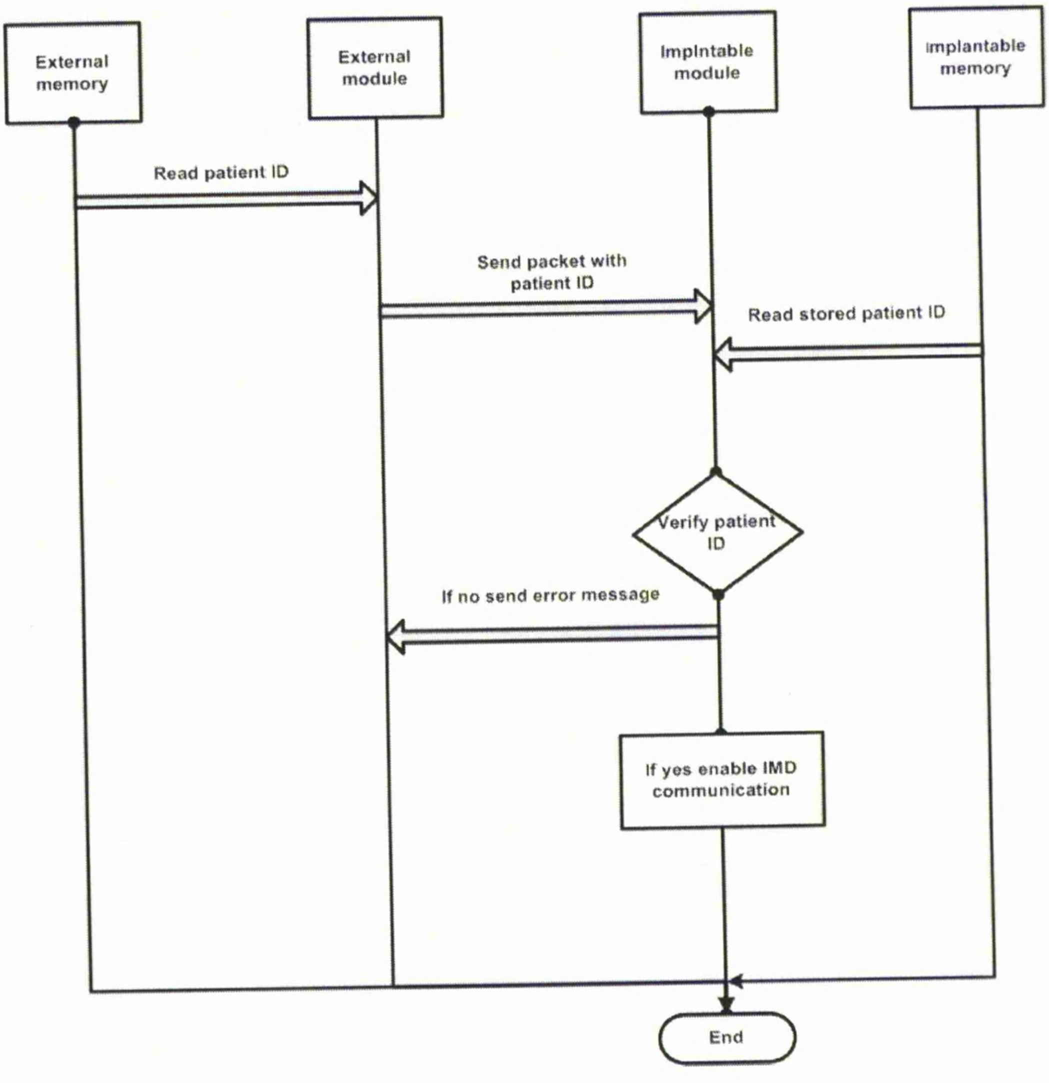



FIGURE 4.9: Verification of patient identification.

(each kit includes two microcontrollers and an RF transceiver) shown in Figure 4.10 are used to test these functions. For all previous tasks, a packets are manipulated between these two kits through transceivers. A remotely reprogramming of implanted shunting system using management shunting protocol system has been done through RF transceiver. Valve schedule parameters were wirelessly sent from external transceiver module then received and stored into implanted transceiver module. The embedded software uses these parameters to replace previous scheduled parameters by the calculated one. In addition, the ICP sensor schedule was calculated based on new valve schedule. Both valve and sensor schedule were used to regulate the valve as well as to collect samples of ICP readings without any error. This reprogramming operation has been done without any effect on the system performance. Furthermore, the operation of wirelessly controlling implanted valve was implemented and tested where, LED which is embedded into MSP430 development kits , was used to simulate the valve function and it is controlled from external by sending a signal to turn on or off this LED. This task was performed as required with high accuracy. The wirelessly non invasive ICP monitoring operation was implemented and tested through these two modules. A packet was send from external module into implanted one that request samples of ICP readings and the implanted parameters. This packet was encoding by the embedded software, then a signal was send to start collecting such samples. A report was prepared and send back to external module. Such report was stored into external RAM and later was used for analysis. This operation was tested and evaluated and it was repeated daily in regular for seven days. The operation was done with high efficiency as required. A closed loop option was activated wirelessly by sending a packet from external module where the embedded software encoded the received packet and send a signal to start collect ICP data. The collected data was used to calculate mean ICP and then compared it with the maximum and minimum thresholds values to open or close the valve based on these values. The valve was regulated as a closed loop for specific time which was determined by the external module then it is returned back to follow the routine schedule.

In emergency scenario test, a samples of ICP readings which were stored in RAM were used to calculate hourly average of mean ICP($H_{avg}$). The $H_{avg}$ was compared with three thresholds values to select the risk factor *i.e.* if $H_{avg}$ greater than 20 and less than 25), the risk factor is 2. In this case, a packet was sent to external module with included this factor. This packet was encoded in external module and acknowledge packet was sent to activate closed loop for five minutes period. Once the time was completed, an auto emergency report was prepared and send to external system. An auto bidirectional communication between two transcivers module was tested and evaluated. As a result, this operation was performed as required and the sequence of proposed design worked properly.

Most of the current shunting system problems would be eliminated using such protocol such as ability of changing the valve schedule after implantation, current ICP monitoring methods problems, availability of ICP clinical data, implanted memory limitation, ability of opening or closing the valve remotely, ability of activate closed loop option wirelessly and power consumption problems. Embedded intelligent software was used to derive the valve and ICP sensor schedules based on dynamic parameters that would be received from external software. By using such protocol, all mechatronic shunting system tasks which were proposed in chapter 2 and 3 were implemented and tested. As a result, the proposed system functions were evaluated and verified with such protocol and that increase of the general safety and reliability of the treatment. The design of this protocol is illustrated in Appended B.

## 4.5 Conclusions

One of the most difficult challenges of using an implantable microcontroller in medical applications is how to access, modify and replace the implanted program. An updating algorithm is used to remotely modify some parameters which are embedded into the microcontroller via RF transceivers. An innovative, bidirectional management shunting protocol was introduced in this chapter for reprogramming

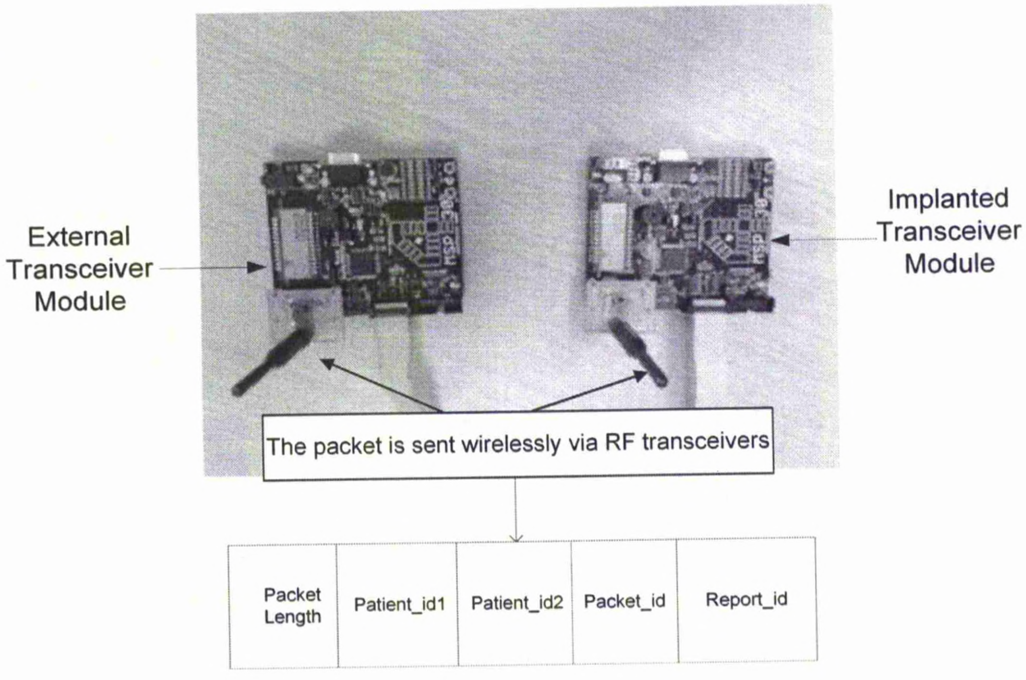



FIGURE 4.10: Prototype of microcontroller and wireless units.

the implantable mechatronic shunting system that lead to management of hydrocephalus. The researcher attempted and success to replace the passive mechanical shunt with a dynamic shunt that would use the management shunting protocol to maximise the potential quality of life for each patient, reduce hospitalisation periods and shunt revisions. Furthermore, a new technique was investigated that would help to circumvent the problem of updating software remotely through RF transceivers.

# Chapter 5

# Parameters for Real-Time Self Shunt Diagnosis[3]

## 5.1 Introduction

Early faults detection in biomedical systems is of vital important in reducing the risk on patient's life. Its important increased in case of implanted system. Leading to increase system reliability, avoid hospitalisation, and reduce patient suffering. The methods used to date for diagnosing shunt malfunctions have been based on clinical presentation of such malfunctions, clinical data, imaging techniques and evaluation of valve function in mechanical terms. Unfortunately, symptoms of various shunt complications can be very similar and difficult to spot thus complicating the diagnosing process.

This chapter presents a method for deriving and selecting shunt faults detection parameters that would be used for early detection and identification of various shunt malfunctions. These parameters were selected based on the strength of their relations with the expected shunt faults. In addition, a method for initial faults recognition was proposed based on these parameters. The effect of various shunt

[3]Part of this chapter has been published under the title "A Real-Time Self diagnosis Method for a Hydrocephalus Shunting System", in 4th Annual Symposium of the Benelux Chapter of the IEEE Eng Med Biol Soc. (EMBS), University of Twente, The Netherlands, Nov 2009.

faults *i.e.* valve blockage, valve leakage, valve disconnection, sensor dislocation and flowmeter fault on simulated ICP were investigated.

Valve blockage is one of the most common shunt malfunctions and it is essential to detect valve blockage in its early stage. This motivated the researcher to find a method for estimating the percentage of blockage and expected time needed to reach full blockage based on ICP data and valve flow measurements. This estimation would help in improving the treatment.

## 5.2 Common Faults

Shunt systems are not perfect devices and complications often arise. Complications may include mechanical failure, infections, obstructions, and the need to lengthen or replace the catheter. Generally, shunt systems require monitoring and regular medical follow up. Shunt malfunction could be due to one of the following reasons: it's blocked with by products of the CSF, some of its components get disconnected, it breaks (usually the distal end), any of the catheters come out of their place, the shunt drains less fluid than it is supposed to or the shunt drains more fluid than it is supposed to.

The symptoms of various shunt complications can be very similar thus complicating the diagnosing process. A shunt is said to be malfunctioning if it is draining at an inappropriate rate. Underdrainage means that insufficient CSF is removed from the ventricles, so that symptoms are not fully alleviated. Also damaging can be overdrainage, which may result in collapse of the ventricles. If this is very rapid, the brain may be torn away from the inner surface of the skull, causing bleeding, which may induce compression of the brain. Less severe overdrainage can result in low ICP with symptoms including severe headaches. Incorrect drainage is often the result of blockage/leakage, either of the catheter or of the tubing. Blockage of the catheter is more common and is a result of a buildup of cells (including those thought to produce CSF) in the holes of the catheter.

Disconnection of the shunt is considered the second most common cause of shunt failure after valve blockage. Disconnection may occur at any site of connection along the course of the tubing. This is usually related to improper technique (loose ligature) or excessive strain along the shunt tube between two points of fixation.

The first monitoring of intracranial pressure was described by Guillaume and Janny in 1951 using an indwelling intraventricular catheter attached to an external strain gauge transducer, amplifying system, and chart recorder [38]. Currently, intracranial pressure sensor is widely used to measure and monitor the intracranial pressure by collecting ICP and sending it via transmitter to the external unit. ICP monitoring has been used to provide reliable data in patients monitored for a short period of time. Common complications of ICP monitoring are infection, haemorrhage and drift [107], *i.e.* a number of studies has found that the fiberoptic monitor has a drift that can be as high as 2-8 mmHg over an 8-day period [13]. The problems of using such monitoring method for a long period of time are the lack accuracy of readings and drift rate may be increased. That would lead to incorrect readings and a reduction in effectiveness of the hydrocephalus management and treatment. The drift of ICP sensor is normally calculated as the difference between the initial and final pressure after a given period of time; thus, it is one of the important parameters since it reveals deviations from the patient's real pressure [24]. The main reason behind the drift of ICP sensor is not fully understood and may be due to the inability to measure constantly the same pressure as a result of mechanical defects of the sensor and the material used [77]. In addition, technical complications occur during using ICP sensor in monitoring ICP such as breakage, dislocation or failure of ICP recording for unknown reasons. These problems also would affect the performance of the shunting system. A method for self diagnosis of the implanted pressure sensor is urgently needed.

Shunt malfunction is one of the most common clinical problems in paediatric neurosurgery. The diagnosis of such malfunctions can be both difficult and perplexing even for the experienced clinician. The methods used to date have been based on clinical presentation of shunt malfunctions, clinical data, imaging techniques and evaluation of valve function in mechanical terms. Unfortunately, symptoms of various shunt complications (seizures, a significant change in intellect, school performance, or personality) can be very similar and difficult to spot thus complicating the diagnosing process. On other hand, the possible presentations of acute shunt malfunction in early stages are innumerable for many reasons such as the lack of non invasive intracranial pressure (ICP) and flow monitoring. In addition, shunt malfunctions might be present even if they have not shown on a CT or MRI scans and also the number of these should be minimised due to the use of radiation and are therefore not desirable for regular use. The early detection and recognition of shunt malfunctions to prevent or minimise complications and maximise shunt functioning has long been accepted as a desirable goal in the treatment of hydrocephalus.

One method of achieving this goal is through the use of real time noninvasive ICP monitoring for hydrocephalus patients. The purpose of this study is to develop an effective method to give endowment to the current implanted shunting system with ICP sensor, flowmeter and transceiver to be able to make a real time self-diagnosis for the shunt. In this method, some features are extracted from intracranial pressure signals which are collected via an implanted ICP sensor and valve flow measurements which are measured using implanted flowmeter. The method uses the expected relationship between ICP feature values and shunt faults. This relationship would be effective in detecting any possible shunting faults at an early stage. A comparison between regularly extracted parameters and their respective reference values (that are dynamically selected based on both valve schedule parameters and initial ICP signals) is carried out. Based on this comparison, an initial decision is made whether a fault exists and its type is identified. The outcome of such method is a shunt diagnosis report that would be wirelessly sent through the transceiver to the external shunting system. By using such method, most of current shunt malfunctions can be initially detected and their types can be identified.

## 5.3 Proposed Methods

Despite ICP monitoring currently being an invasive procedure, patients with hydrocephalus may need repeated episodes of monitoring months or years apart. This is a result of problems arising in which ICP readings are needed for patient and shunt diagnosis. The invasive nature of ICP monitoring has motivated researchers to develop a telemetric implantable pressure sensor for short- and long-term monitoring of ICP with high accuracy [35]. Such sensor was mainly used for monitoring ICP wirelessly by the physician who could manually adjust the valve settings accordingly. In addition, a flowmeter for hydrocephalus patients is under development [35]. Such flowmeter would be necessary to provide important measurements to verify that the shunt system is working properly and not causing harm to the patient. Numerical simulation has been performed using Simulink model that reproduce intracranial hydrodynamics of acute hydrocephalus patients using historical ICP data. All expected shunt faults have been simulated using Simulink'$^{TM}$.

In this chapter, a technique is illustrated that focuses optimising the use of intracranial pressure measurement for successful diagnosis of valve and sensor malfunction. Figure 5.1 shows a valve schedule for 24 hours. This schedule would be used to manage the shunting system by regulating the valve , whereas the ICP sensor is used to collect ICP readings based on such schedule. To optimise the usefulness of the ICP readings and monitor the change in ICP due to opening the valve, the ICP sensor would collect samples of ICP few seconds before the valve is opened and closed. These ICP readings are used to extract various parameters that would help in detecting any faults or blockage in the valve. In addition, the ICP sensor is used to collect the ICP readings in the middle of each close duration. These readings are used to detect any intermittent faults in the valve during the closed period, *i.e.* the valve should be closed in this time based on the valve schedule, but it may not be responding to the closing signal for many reasons such as valve leakage due to mechanical or electrical fault.

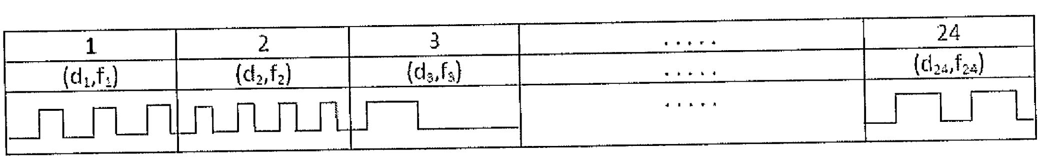



FIGURE 5.1: Time based valve.

### 5.3.1 Blockage Factor Estimation

Valve blockage is one of the most common malfunctions that occur. It is essential to detect the blockage in its early stage, thus the percentage of the blockage in the shunt is determined. This would give an indication of how critical the situation is in order to help in solving the problem before a full blockage occur. The percentage of the blockage in the valve can be estimated based on the valve resistance, rising in resistance due to blockage, valve flow and the valve flow due to blockage. This operation is illustrated as follows.

The rate of change in total ventricle volume $V$ is given by the following equation.

$$\frac{\Delta V}{\Delta t} = Q - q \tag{5.1}$$

where Q is the net excess CSF produced per minute and q is the valve flow.

Valve flow before blockage ($f_b$) is represented by,

$$f_b = \frac{ICP}{R_v} \tag{5.2}$$

where $R_v$ is the valve resistance ($R_v$=263.763 mmHg per ml/*second*) [30].

Valve flow after blockage ($f_a$) is given by,

$$f_a = \frac{ICP}{R_v + R_b} \tag{5.3}$$

where $R_b$ is the rise in resistance due to blockage.

As a result of simulation, it can be noticed that the blockage effect start when ($R_b = R_v$) and for any value of ($R_b$) less than ($R_v$) the blockage effect is minimal. Based on this, it is assumed that the initial value of $R_b$ is equal to $R_v$ and $R_b$ is always a multiple of $R_v$. The total resistance after blockage ($R_A$) can be calculated as follows:

$$R_A = R_v + (N \times R_b) \tag{5.4}$$

where $N$ is the blockage factor.

The ratio of valve resistance before blockage ($R_b efor$) to valve resistance after blockage ($R_f ter$) is calculated as follow,

$$\frac{R_a fter}{R_b efor} = \frac{R_v \times (1 + N)}{R_v} \tag{5.5}$$

Thus, the percentage of blockage resistance can be represented by $(1 + N) \times 100\%$. The percentage change in total resistance due to blockage is presented by blockage factor (N) and is calculated using the following equation,

$$\frac{R_a fter - R_b efor}{R_b efor} = \frac{R_v \times (1 + N) - R_v}{R_v} = N \times 100\% \tag{5.6}$$

Based on these calculations, the percentage of valve blockage can be estimated and used as a fault detection parameter in the proposed method.

### 5.3.2 Parameters Extraction

In this study, the following parameters were investigated: a change in volume over open duration, rate of ICP change over open duration, mean absolute deviation (MAD) of ICP, average power of ICP signals, mean amplitude of ICP signal, root mean square (RMS) of ICP and valve blockage percentage factor ($N$). A statistical analysis was performed on these parameters. As a result, the relationship between the values of these parameters and the blockage degree, represented by blockage factor ($N$), is investigated. In order to achieve such goals and select suitable parameters for this study, these parameters were calculated for shunted hydrocephalus patients in normal case without any faults or blockage in the valve. Therefore, different degrees of valve blockage ($N$=1 to 50) were simulated and these parameters were calculated for these cases. The parameters which have strong correlation with blockage factor or rising ICP were selected as shunt faults detection parameters for this study.

The following steps explain and illustrate the selected parameters calculation:

- For each period, calculate mean ICP when valve is open ($\overline{ICP}_{i1}$), closed ($\overline{ICP}_{i2}$) and the middle of the closed duration ($\overline{ICP}_{i3}$),

$$Mean = \frac{\sum_{i=1}^{n} ICP(i)}{n} \tag{5.7}$$

where $ICP(i)$ is the sample of collected ICP readings and $n$ is the number of ICP readings (600 readings per sample).

- Calculate rate of ICP change ($\frac{\Delta ICP_1}{\Delta t}$) over open duration ($d$),

$$\frac{\Delta ICP_1}{\Delta t} = \frac{\overline{ICP_{i2}} - \overline{ICP_{i1}}}{d} \tag{5.8}$$

- Calculate rate of ICP change ($\frac{\Delta ICP_2}{\Delta t}$) at the middle of closed duration,

$$\frac{\Delta ICP_2}{\Delta t} = \frac{\overline{ICP_{i3}} - \overline{ICP_{i1}}}{(p-d)/2} \tag{5.9}$$

- Calculate rate of ICP change ($\frac{\Delta ICP_3}{\Delta t}$) for closed duration (p-d).

$$\frac{\Delta ICP_3}{\Delta t} = \frac{\overline{ICP_{(i+1)2}} - \overline{ICP_{i1}}}{p - d} \tag{5.10}$$

- Calculate mean absolute deviation (MAD) for each sample of ICP readings,

$$MAD = \frac{\sum_{i=1}^{n} |(ICP(i) - \overline{ICP})|}{n} \tag{5.11}$$

- Calculate the total average power in time domain (TAP) for each sample of ICP readings,

$$TAP = \frac{\sum_{i=1}^{n} |(ICP(i))|^2}{n} \tag{5.12}$$

- Calculate mean peak to peak amplitude for ICP signals,

$$ICP_{p-p} = \frac{\sum_{i=1}^{n} ICP(i)_{max} - ICP(i)_{min}}{n} \tag{5.13}$$

where $ICP(i)_{max}$ is the upper peak value of ICP signal and $ICP(i)_{min}$ is the lower peak value.

- Calculate root mean square ($RMS$) for each sample of ICP readings,

$$RMS = \frac{\sqrt{(\sum_{i=1}^{n}(ICP(i)^2))}}{n} \tag{5.14}$$

The previous parameters were calculated for both normal and faulty shunt situations. It is noticed that most of these parameters such as mean ICP, rate of ICP change, mean absolute deviation, and mean peak to peak were effected by rising of ICP due to various faults. Such parameters were selected as fault detection parameters. A list of the extracted ICP parameters are shown in Table 5.1

### 5.3.3 Sensor Complications Detection

The proposed method focuses on optimising the use of ICP measurement in diagnosing ICP sensor complications by deriving some parameters and performing statistical measurements that would help in early detection of any fault or complication. As it is mentioned in the previous section, the ICP sensor would play a vital role in managing of hydrocephalus. In this method, the ICP sensor is managed to collect the ICP readings for each hour for a number of times . These readings are used to extract some important parameters that would help in detecting any fault or complication in the ICP sensor.

A drift detection method is proposed based on the selected ICP parameters. One of the most important parameters for detecting any drift in the ICP sensor is the deviation of the measured readings from the zero drift that would be given by the manufacturer's specification. Thus, monitoring ICP sensor for an initial period after shunt implantation is needed. This monitoring would lead to measure and calculate the selected ICP parameters such as $TAP$, MAPD, MAD and Mean $ICP_{p-p}$. These values would be used as reference values in the proposed method to reflect the healthy case of ICP sensor.

These parameters would be calculated for each ICP sample, then the average of each hour for all these parameters would also be calculated as well as the average for 24 hours. This operation would be repeated every day for 10 days. The root

TABLE 5.1: A list of extracted ICP parameters

| Extracted Parameters | Calculation |
| --- | --- |
| Mean ICP | $MeanICP = \frac{\sum_{i=1}^{n} ICP(i)}{n}$ |
| Rate of ICP change | $\frac{\Delta ICP_1}{\Delta t} = \frac{\overline{ICP_{i2}} - \overline{ICP_{i1}}}{d}$ |
| Rate of ICP change(open duration) | $\frac{\Delta ICP_1}{\Delta t} = \frac{\overline{ICP_{i2}} - \overline{ICP_{(i1}}}{d}$ |
| Rate of ICP change(closed duration) | $\frac{\Delta ICP_3}{\Delta t} = \frac{\overline{ICP_{(i+1)1}} - \overline{ICP_{i2}}}{p-d}$ |
| Rate of ICP change(middle of closed duration) | $\frac{\Delta ICP_2}{\Delta t} = \frac{\overline{ICP_{i3}} - \overline{ICP_{i2}}}{(p-d)/2}$ |
| MAD of ICP | $MAD = \frac{\sum_{i=1}^{n} \lvert (ICP(i) - \overline{ICP}) \rvert}{n}$ |
| TAP of ICP | $TAP = \frac{\sum_{i=1}^{n} \lvert (ICP(i)) \rvert^2}{n}$ |
| Mean peak-to-peak amplitude | Mean $\text{ICP}_{p-p} = \frac{\sum_{i=1}^{n} ICP(i)_{max} - ICP(i)_{min}}{n}$ |
| RMS of ICP | $RMS = \frac{\sqrt{(\sum_{i=1}^{n} (ICP(i)^2))}}{n}$ |
| Rate of change in volume | $\frac{\Delta V}{\Delta t} = Q - q$ |
| Total resistance after blockage | $(R_A) = R_v + (N_b)$ |
| Blockage factor | $N$ |
| Percentage of Blockage resistance to valve resistance | $(1 + N) \times 100\%$ |
| MAPD of ICP | $MAPD = \frac{\sum_{i=1}^{n} (ICP_{measured}(i) - ICP_{reference(i)})}{n}$ |
| MAE of ICP | $MAE = \frac{\sum_{i=1}^{n} abs(ICP(i)_{reference} - ICP(i)_{calculated})}{n}$ |
| FoM | $FoM = \frac{\text{Total abnormal drift index}}{\text{Total number of measuring}}$ |

mean square error (RMSE) and mean absolute error (MAE) would be calculated for the zero drift case. Then these parameters are used as a reference to detect any drift by comparing the daily measured average with this value and find the drift index of the ICP sensor which is the difference between the initial (zero drift) and the final pressure after a period of time. This index would be taken into consideration during the management and treatment of hydrocephalus and also in self diagnosis of the shunt.

Other important complications of the ICP sensor that are modelled are sensor breakage and dislocation. Breakage and dislocation complications usually occur during nursing procedures or medical monitoring or may be for any unknown reasons, and are usually detected by a sudden loss of sensor signal [99]. To detect such complications, peak-to-peak amplitude of ICP signals is calculated ($ICP_{p-p}$). In case the value of $ICP_{p-p}$ is zero or close to zero, a proposed ICP component detection technique is used to detect the ICP signal components. The ICP signal is mainly consists of four part, percussion peak (P), tidal peak (T), dichrotic notch (N), and dichrotic peak (D) [1]. Figure 5.2 shows these components. Therefore, if the components are detected, the sensor is properly working. Otherwise, if the components are not detected, this confirms that there is a breakage or dislocation in the ICP sensor.

The ICP component detection technique was implemented and used to detect the components of ICP signal with high accuracy. The following procedure explains the method of detecting any ICP sensor complications,

- Calculate the maximum absolute deviation of the measured ICP signals,

$$MAPD = \frac{\sum_{i=1}^{n} |ICP_{measured}(i) - ICP_{reference(i)}|}{n} \tag{5.15}$$

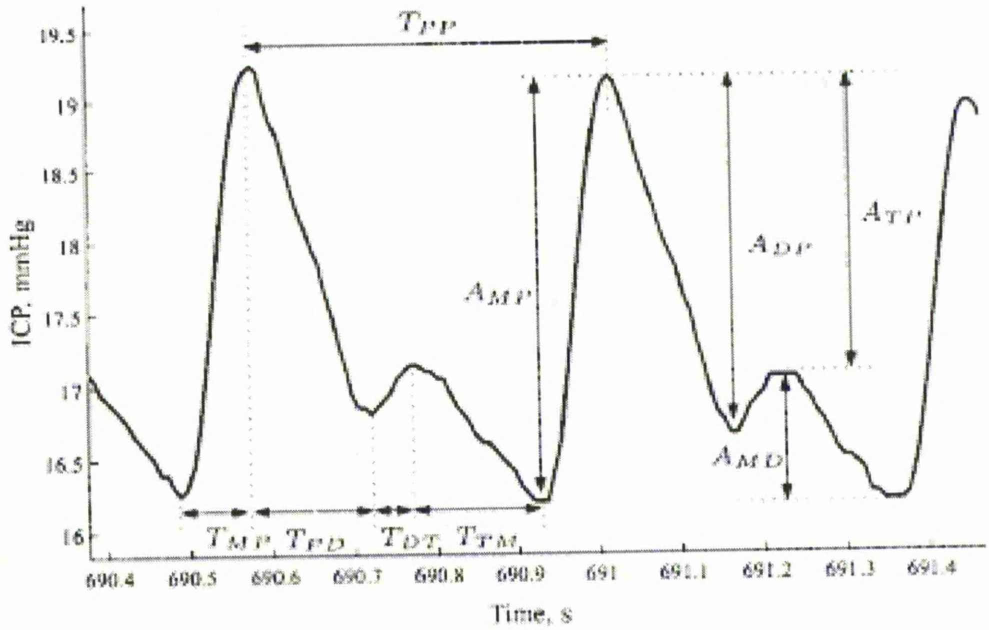



FIGURE 5.2: The components of ICP signal [1].

where $ICP_{reference(i)}$ is the measured ICP during initial period after implanted the sensor.

- Calculate the percentage of changing in pressure during an initial period (10 days) of implanting the shunt (zero drift case) as follow:

  Calculate mean absolute deviation (MAD) for each ICP sample,

$$MAD = \frac{\sum_{i=1}^{n} |(ICP(i) - \overline{ICP}|)}{n} \tag{5.16}$$

Calculate mean absolute error (MAE) for each sample of ICP readings and for all previous parameters,

$$MAE = \frac{\sum_{i=1}^{n} abs(ICP(i)_{reference} - ICP(i)_{mesured})}{n} \tag{5.17}$$

- Calculate figure of merit to find out how many times the ICP sensor had drift in pressure readings during the initial period,

$$FoM = \frac{\text{Total abnormal drift index}}{\text{Total number of measuring}} \tag{5.18}$$

where drift index is the difference between the calculated value and the reference values for each selected parameter.

- It can be said that the drift index is abnormal if:

$$\text{Drift index} > \text{Acceptable Error} \tag{5.19}$$

where acceptable error value is depend on sensor type.

- After doing these measurements, it is possible now to predict the drift index and the percentage of pressure change for each day during the initial period
- Add the value of drift index to each ICP measurement before using it in any management or treatment of hydrocephalus or in shunt diagnosis.
- Store the results of $FoM$ in the implanted microcontroller and later these values can be used as a reference values before deciding whether or not there is a drift in the ICP sensor.
- Calculate mean peak to peak amplitude for ICP signals ($ICP_{p-p}$)

$$\text{Mean ICP p-p} = \frac{\sum_{i=1}^{n} ICP(i)_{max} - ICP(i)_{min}}{n} \tag{5.20}$$

- Apply the ICP signal components (P,D,N,T) detection technique to verify that the recorded signal is presented as a real ICP signal or not.

### 5.3.4 Shunt Faults Detection

Based on previous calculations, the relations between the extracted ICP parameters and simulated faults are identified. The parameters which have strong relations with expected shunt faults have been selected and calculated for each collection of ICP sample such as Mean ICP, MAD and Mean ICP peak-to-peak amplitude. These parameters were calculated for 6-second time windows.

Hydrocephalus flowmeter would also be used in detecting shunt faults to measure the valve flow rate when the valve opens. This measurement would play a vital role in identifying shunt faults. For example, in valve disconnection fault the value of flow rate would be zero, even though the status of valve is open. This change in the flow rate would be used as indication to such fault. Same thing in blockage case, the value of flow rate would be reduced due to the blockage then it would be close to zero and this dramatic changing would also be used to give an indication of blockage fault.

A set of reference values for selected parameters and flow rate are used to present the initial state of the system. Various situations have been considered such as no fault, valve blockage, valve disconnection and ICP sensor dislocation. The values of these reference parameters are derived based on the current valve schedule and they are dynamically changed whenever the schedule is changed. Numerical simulation has been used to estimate these values.

A set of rules is also used which encompasses all expected faults that should be considered within the scope of this problem. For each valve open period, the ICP samples which are collected few seconds before the start and end of this period, would be used to calculate the current values of the selected parameters. The calculated values would be classified based on reference values (illustrated in Table 5.2) to identify the current status of this open period. Figure 5.3 presents a block diagram of the procedures of initial self diagnosis technique which is used in the proposed method. This method is based on a number of conditions that are used to determine whether a problem exists or not. Each open period of the valve schedule would be tested in real time and the result of the test would be saved in implanted memory.

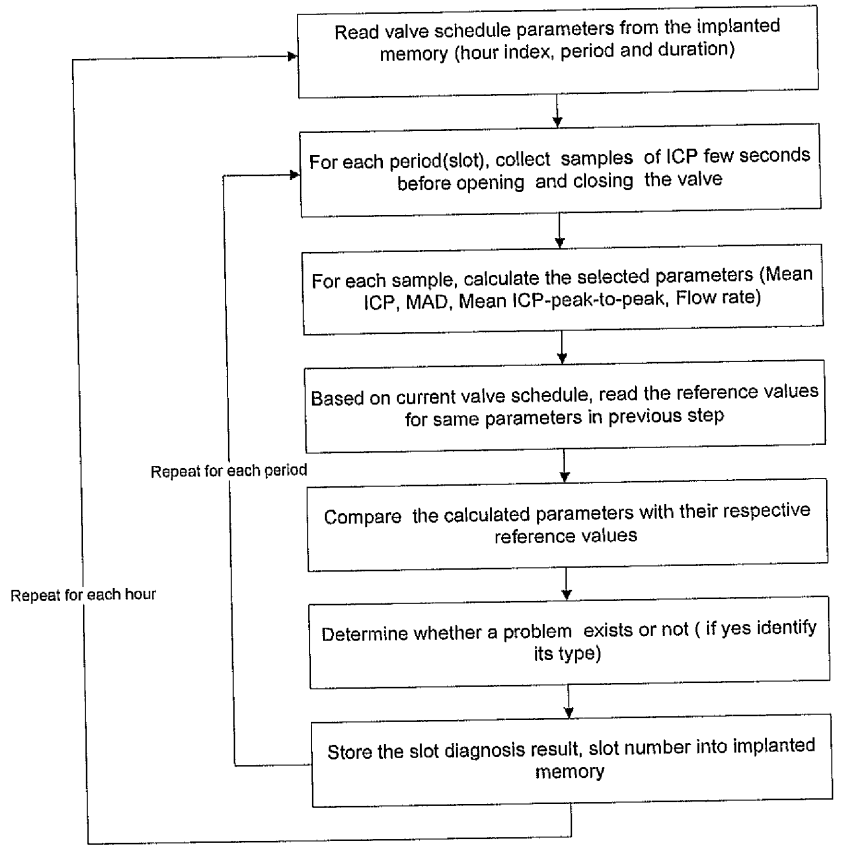



FIGURE 5.3: A block diagram of the procedures of self diagnosis technique.

To improve the efficiency of the self diagnosis technique, a figure of merit has been used to find out the percentage of abnormal periods (slots) to the number of total slots over 24 hours as follows,

$$FOM1 = \frac{\text{Total abnormal slots}}{\text{Total number of slots}} \times 100\% \tag{5.21}$$

It can be said that the slot is abnormal if:

$$|\text{Calculated parameter} - \text{Reference parameter}| > \text{Acceptable Error} \tag{5.22}$$

The result of this calculation would be stored in implanted microcontroller and sent to the external system then used as a historical database for shunt diagnoses. The outcome of the proposed method is a daily report that includes the initial results of daily shunt self-diagnosis such as slot number, fault type and fault time. This report will be sent via implanted transceiver to the external. This will help in early detection of any shunt malfunction thus reducing the risk of brain injury or, in some cases, death, and finally keep the patient life safer than before. The disadvantage of such proposed method is its accuracy because it is mainly depends on estimated selected parameters values.

## 5.4 Results and Discussion

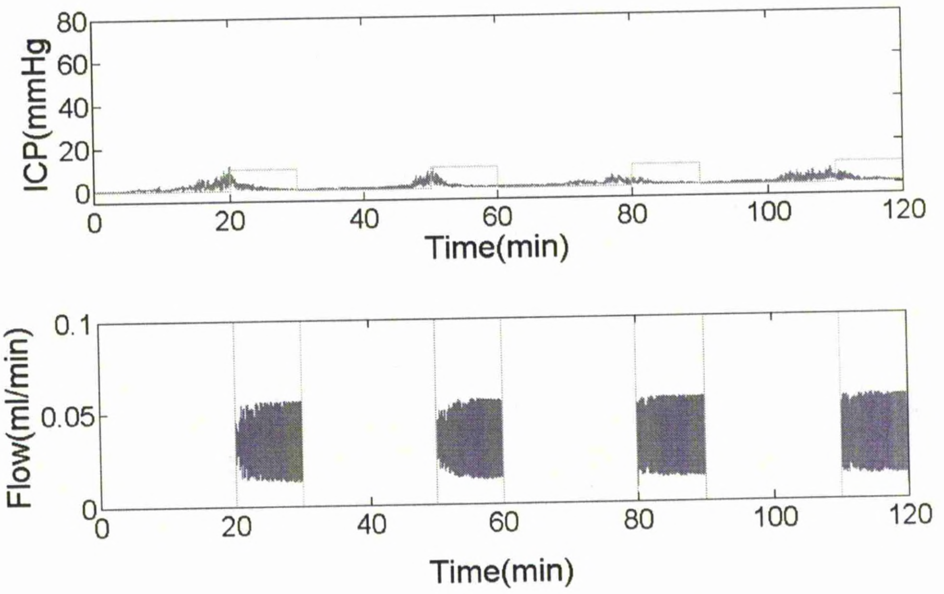
Numerical simulation has been performed using Simulink model that reproduces intracranial hydrodynamics of acute hydrocephalus patients using historical ICP data. All expected shunt faults, *e.g.* blockage, valve disconnection, sensor dislocation, have been simulated. Figures 5.4 and 5.5 illustrate the effect of these faults on the ICP traces and flow measurements. The values of the selected parameters which were calculated in real time for each window were compared with the reference values for same parameters under different conditions. The proposed method is applied for all simulated faults and they were initially recognised using a rule-based system. The outcome of such method is a statement which include the results of daily shunt self-diagnosis. Figure 5.8 shows such a statement.

A Simulink model with Matlab graphical user interface has been used to simulate different degrees of valve blockage. The presence of any blockage is detected by comparing the values of ICP and flow parameters which are calculated in real time with the reference values of these parameters.

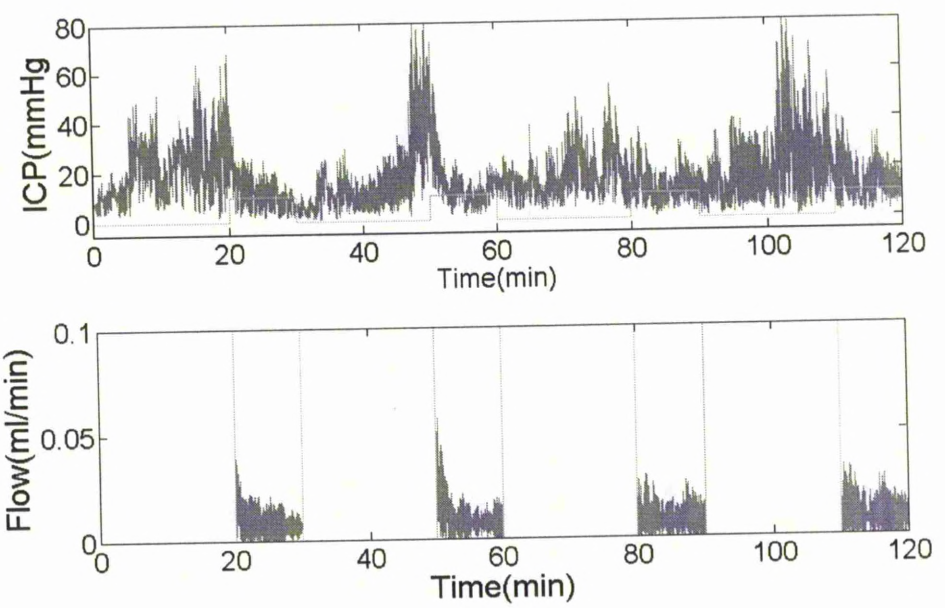
The rule based system is used to detect and classify such problem by predicting the periodic variations in ICP parameter values and investigating the case where flow is currently absent. Figures 5.6 and 5.7 show ICP traces for shunt at different degrees of blockage over 2 hrs. The percentage of blockage in the valve should be determined, to give an indication of how critical the situation is. That would also be helpful to solve the problem before a full blockage occurs. The percentage of the blockage in the valve is estimated based on the blockage factor which was illustrated in previous section.

Simulation results agreed with the expected effect of introducing blockage into the shunting system. The recorded ICP data were collected at 100Hz sample rate and processed by the fault detection code. This code has been developed to derive the required parameters. Statistical measurements have been also done to calculate and derive other parameters. The relations between these parameters and valve blockage are derived and the results were displayed in Figures 5.9, 5.11, and 5.13.

An initial period of 24 hours after implanting the shunt has been simulated and the ICP data was recorded then used to derive and calculate the values of reference parameters that were used for the diagnosis purposes. Table 5.2 illustrates the estimated reference values when valve opens two times per hour for a duration of

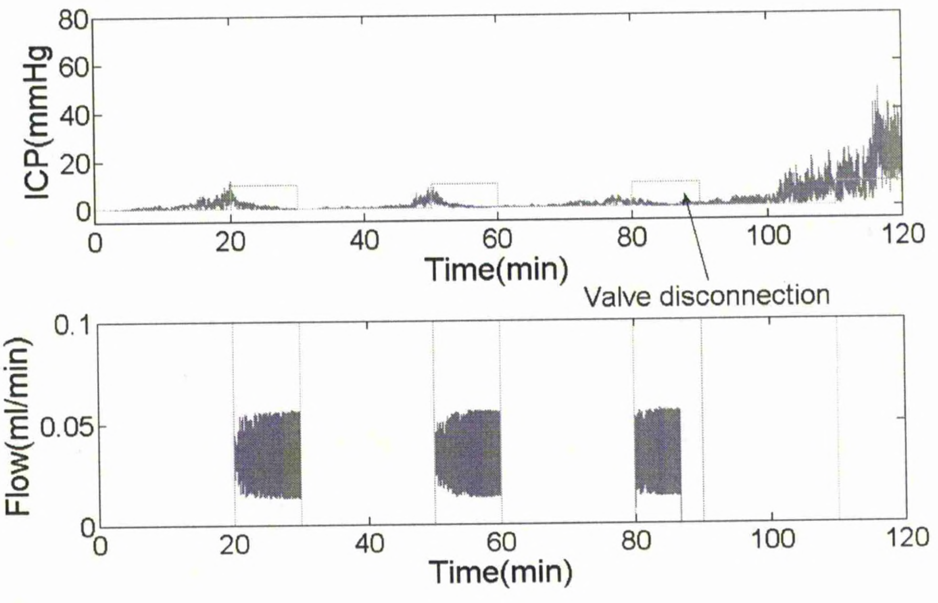



(a)

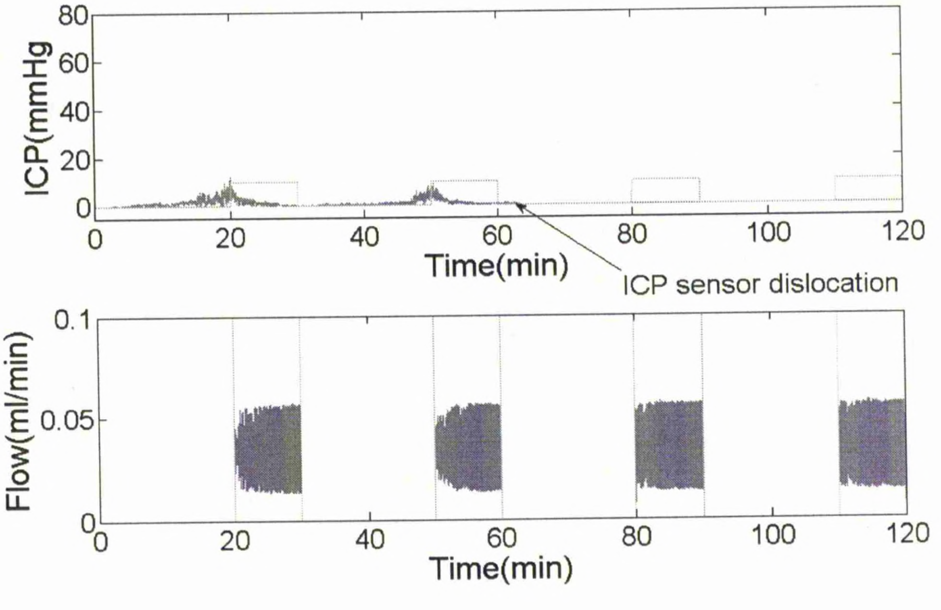



(b)

FIGURE 5.4: ICP and flow rate traces for various simulated shunt faults; (a) No fault and (b) Partial shunt blockage.

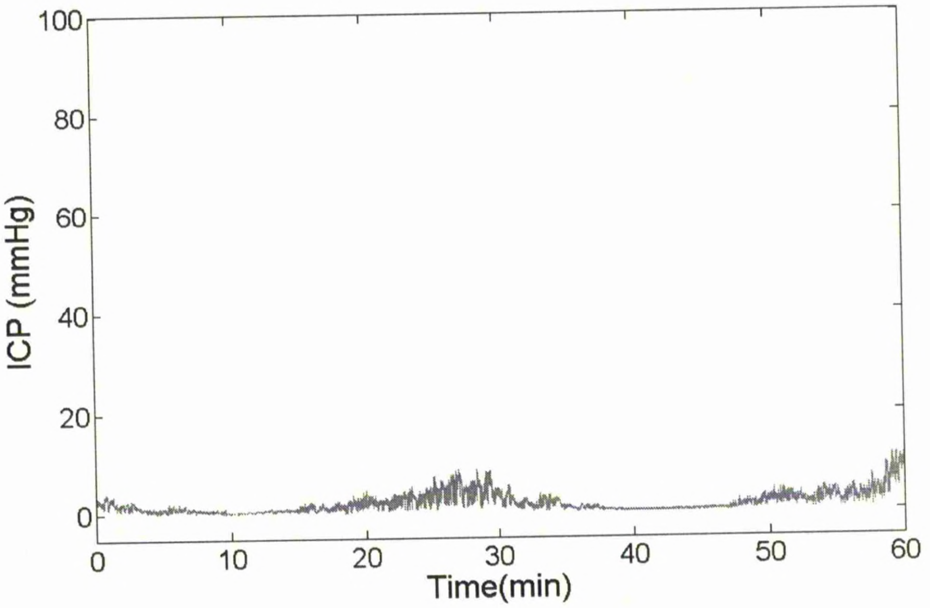



(a)

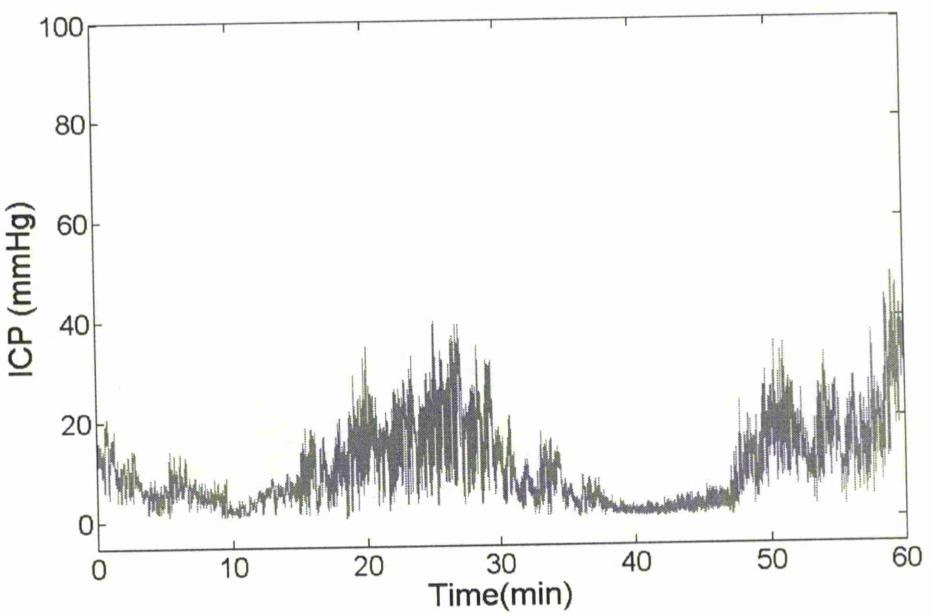



(b)

FIGURE 5.5: ICP and flow rate traces for various simulated shunt faults; (a) Valve disconnection and (b) ICP sensor immigration.

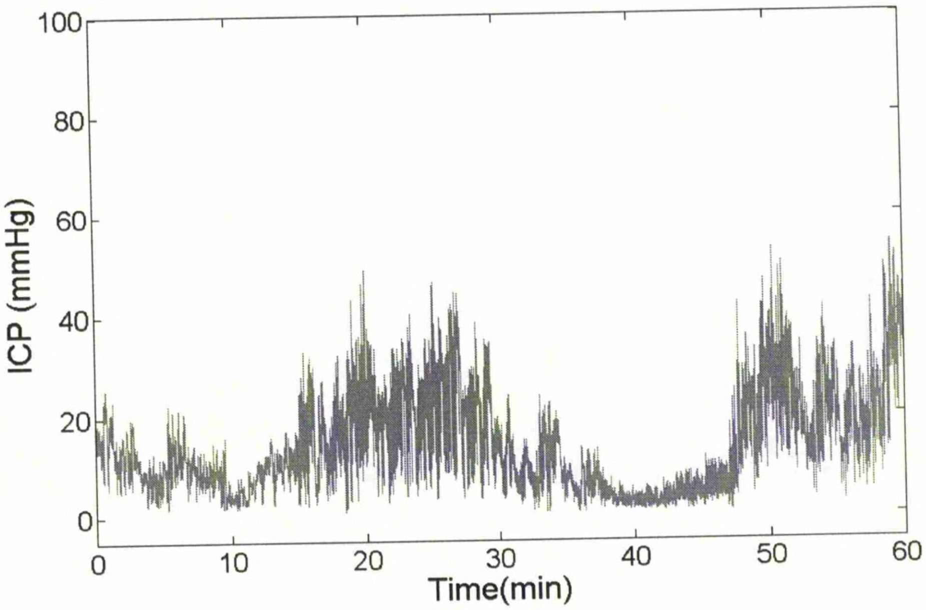



(a)

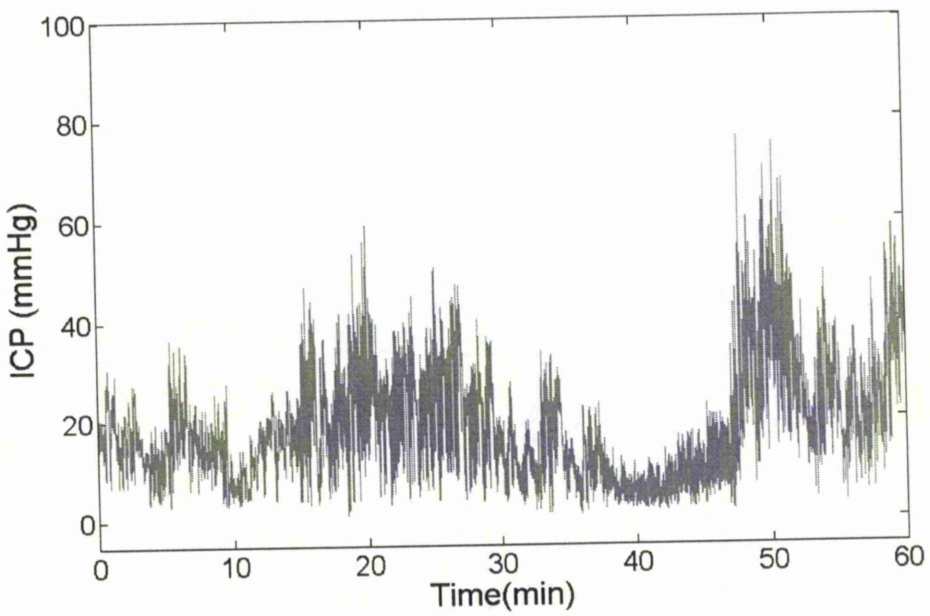



(b)

FIGURE 5.6: The relation between ICP and blockage factor (N); (a) N=0 and (b) N=1




(a)




(b)

FIGURE 5.7: The relation between ICP and blockage factor (N); (a) N=2, and (b) N=5.

```
=================================================================
A Real-Time self Diagnosis for a Hydrocephalus Shunting System
                    Diagnosis Report
=================================================================
Date:
Time:
Open Valve Duration = 10 min
Close Valve Duration = 20 min
Patient Identification Number:-
-----------------------------------------------------------------

Slot Number                              Fault Type
-----------------------------------------------------------------
    1                                 No fault
    2                                 No fault
    3                                 No fault
    4                                 Valve disconnection
    5                                 Valve disconnection
    6                                 Valve disconnection
    7                                 Valve disconnection
    8                                 Valve disconnection
-----------------------------------------------------------------
```

FIGURE 5.8: A sample of an output statement for self diagnoses method in case of valve disconnection fault.

ten minutes.

TABLE 5.2: An estimated reference values of parameters at different shunt conditions.

| Estimated Parameters | Normal state | Valve blockage | Valve disconnection | ICP sensor dislocation | Flowmeter faults |
|---|---|---|---|---|---|
| Mean ICP | 1-7 (mmHg) | >10 | >10 (mmHg) | 0 (mmHg) or unknown signal | 1-7 (mmHg) |
| MAD | 0.2-2.5 (mmHg) | >2.5 (mmHg) | >2.5 (mmHg) | 0 (mmHg)or unknown signal | 1-7 (mmHg) |
| Flow rate | 0.05-0.2 (ml/min) | 0.001-0.05 (ml/min) | 0 (ml/min) | 0.05-0.2 (ml/min) | 0 (ml/min) |

The blockage factor is derived. In addition, the ratio of new overall resistance to standard resistance (1+N) was calculated.

A fixed valve schedule was used, that opens for 10 minutes twice an hour. From Figures 5.6 and 5.7, it can be noticed that the degree of ICP oscillation, amplitude of ICP signals and mean ICP were increased due to the increase in blockage factor. This increase is caused by a fault or blockage in the valve. In no blockage case $R_b$

equals zero, while in case of blockage $R_b$ is assumed to be greater than $Rv$. And as expected, the valve flow rate was reduced due to blockage.

As blockage increased, the rate of ICP change, valve flow and change in volume are initially increased since the effect of the increase in ICP was stronger than that of valve resistance, Valve Flow= $\frac{ICP\uparrow}{R_v\uparrow}$. This increase is followed by continuous decrease starting from the point at which the value of $R_v$ is increased due to a blockage by value $R_b$. The value of valve resistance is increased by $N$ factor due to blockage.

In this method, the percentage of blockage through the valve can be calculated based on a comparison between the calculated rate of ICP change with a reference one. In this case, the author is interested in the quantity of overall decrease in ICP over the open duration. Thus, the shape of the path between the starting and ending ICP values over open duration is irrelevant at this point. As a result, the rate of ICP change at the beginning and ending of open duration have been used to calculate a percentage of blockages. For the volume calculation, it is known that the volume is function of flow and since flow of the valve is changing instantaneously within the opening period due to the decrease in ICP (no blockage), thus the shape of path followed by the ICP is important. In this work the path is assumed to be linear and presented by average flow. To validate this assumption, the volume using the instantaneous flow was calculated and the total volume over opening duration would be the summation of these instantaneous volumes. At the same time, an average volume was calculated using the average flow and then compared with the summation of the instantaneous volume.

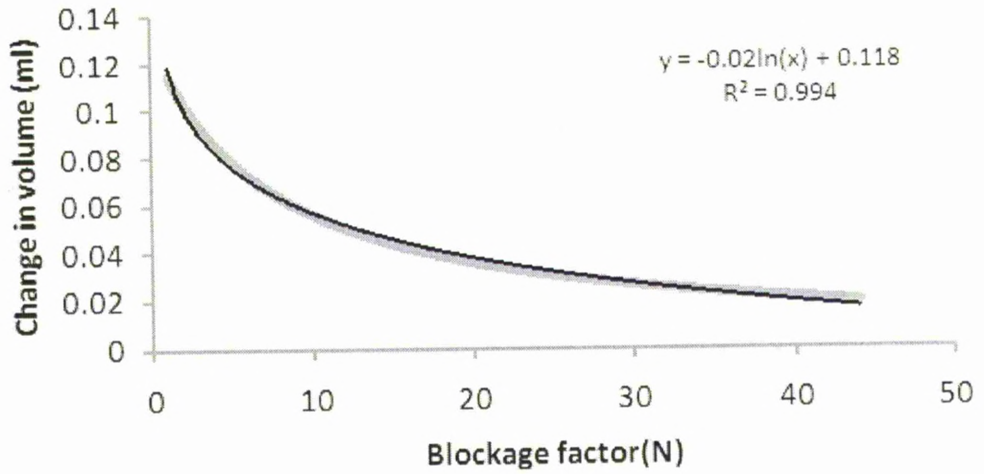
The difference between the values of calculated volume was small but not negligible. But it was noticed that the pattern of change in both cases is similar. Thus for the purpose of this study, the average volume could be used as an indicator of the variation in the volume.

Theoretically at full blockage, the valve resistance should be infinite to prevent CSF flow. But it has been noticed that the value of blockage factor ($N$) that results in full blockage in the valve is sensitive to the open duration, *e.g.* when open duration equals ten minutes the value of $N$ that leads to full blockage is 50. This means that the total resistance of the valve due to a full blockage is ($R_v$ + $50 \times \mathrm{R}_b$).

The relation between the change in volume over open duration, the rate of ICP over open duration, the maximum absolute deviation over open and closed durations, and the mean peak-to-peak amplitude of ICP with blockage factor(N) were medelled using logarithmic minimum square root fit as shown in Table 5.3 and in Figures 5.9, 5.10, 5.11 and 5.12. From the trends of these parameters, it has been noticed that the relations are very strong. Thus it can be concluded these parameters are strongly affected by blockage. As a result, the implanted code would used these parameters for detecting valve blockage.

In addition, it can be concluded that the rate of ICP over closed duration can be used for detecting any intermittent faults in the valve during closed period such as, valve not responding to the controlling signal or valve leakage. On the other hand, MAPD and mean peak-to-peak amplitude of ICP over open and closed durations can also be used for detecting any sensor complications such as sensor breakage or dislocation.

In addition and to make the proposed technique more efficient, the relations between the hourly average of these parameters as well as over 24 hour with blockage factor have been calculated. Figures 5.13 and 5.14 show the relations between the values of these calculated parameters and the blockage factor. From the trends of these parameters,it has been noticed that the relations are strongly effect by

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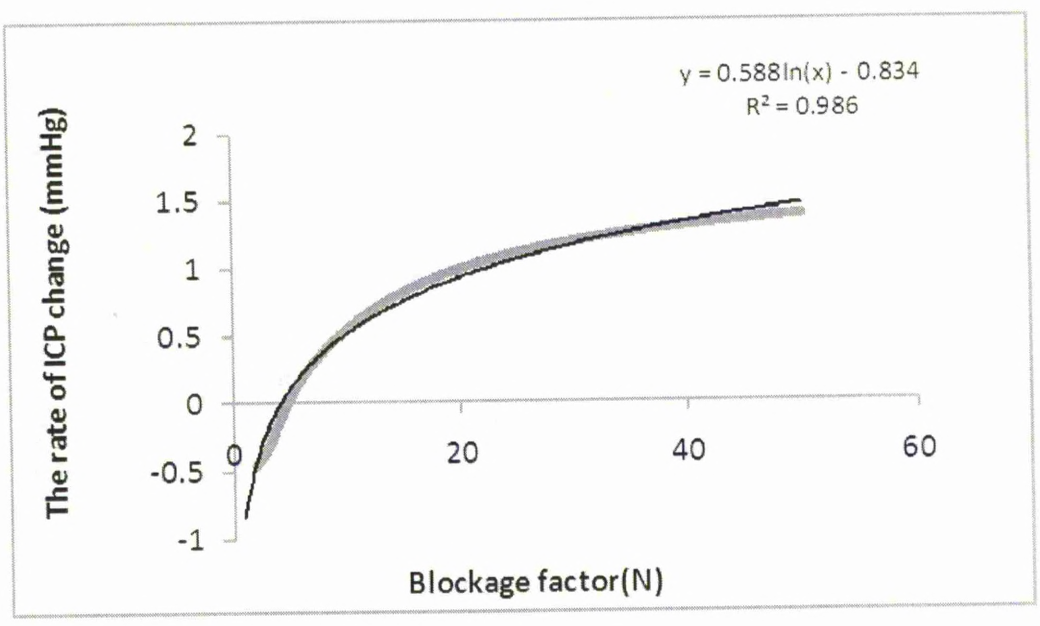
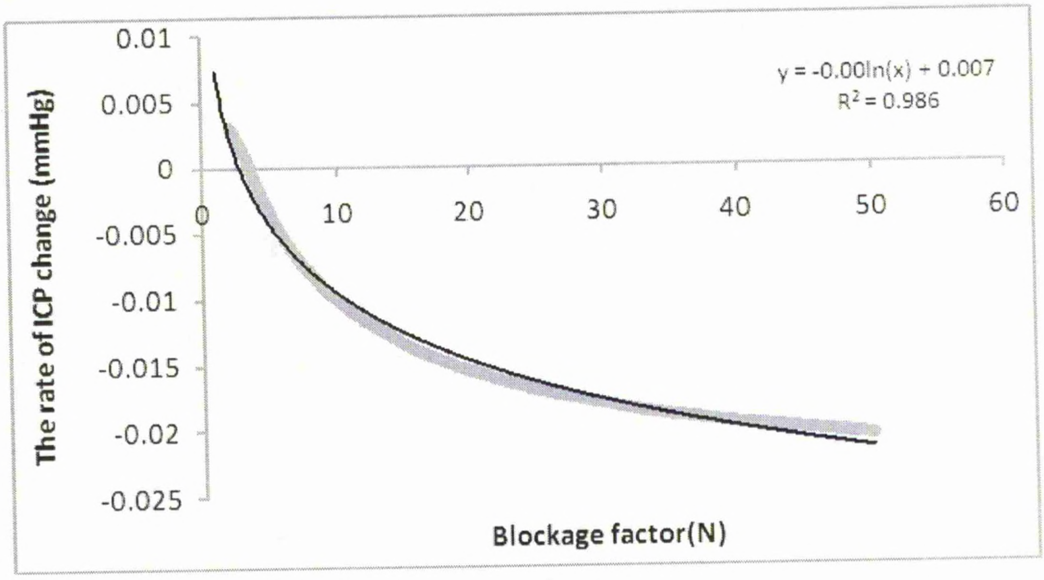



(b)

FIGURE 5.9: The relations between blockage factor and calculated ICP parameters; (a) Change in volume over open duration and (b) Rate of ICP change over open duration, black line present the line best fit.

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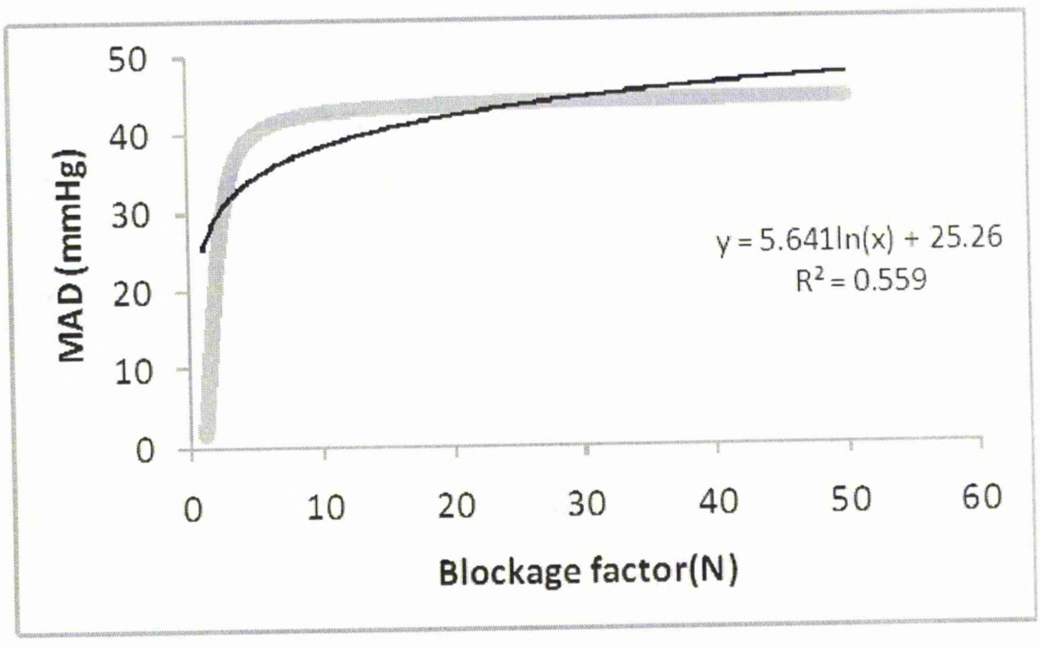


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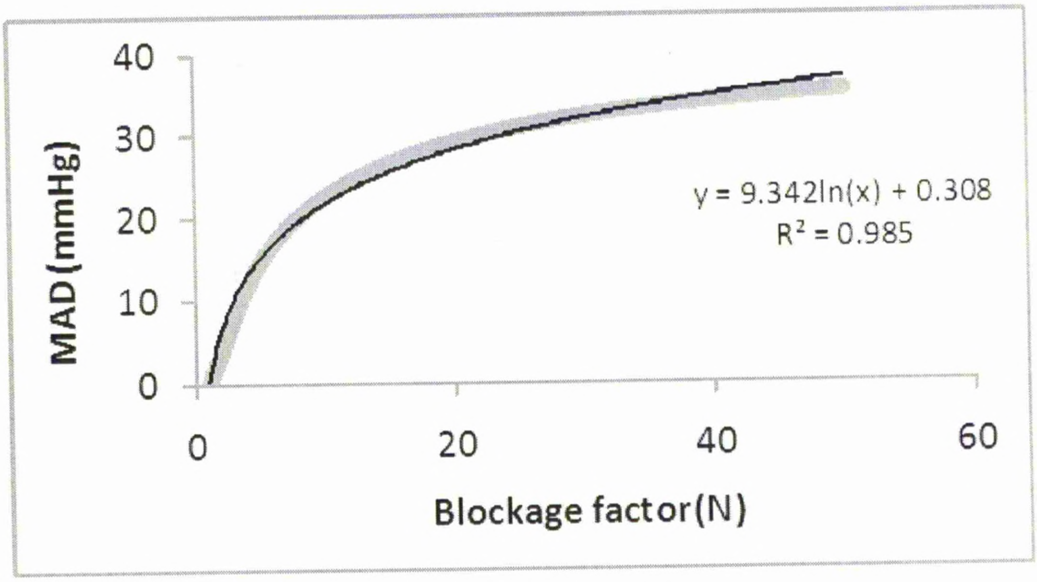
FIGURE 5.10: The relations between blockage factor and calculated ICP parameters; (a) Rate of ICP change over close duration and (b) Change in MAD over open duration, black line present the line best fit.

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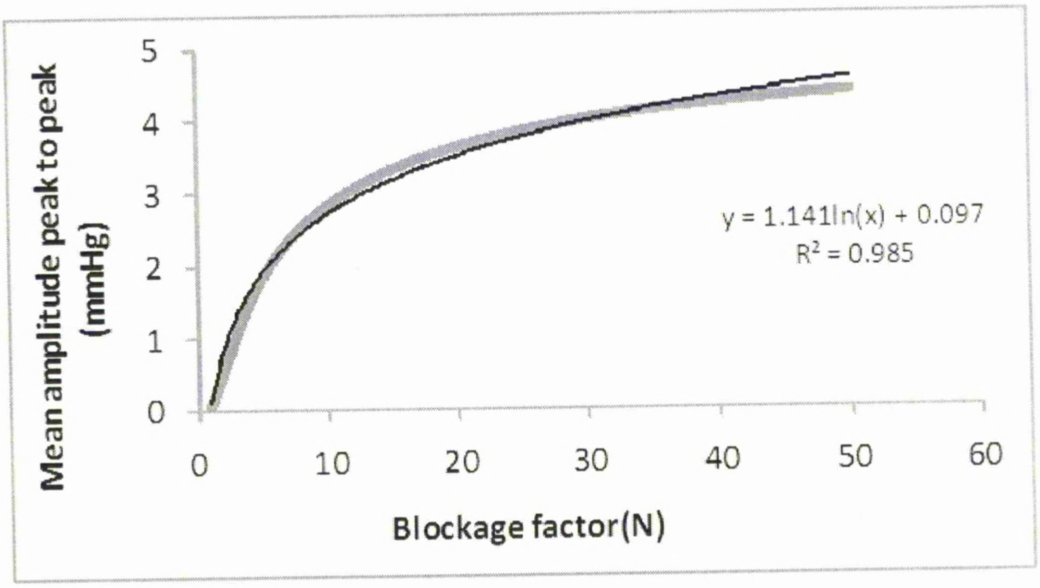


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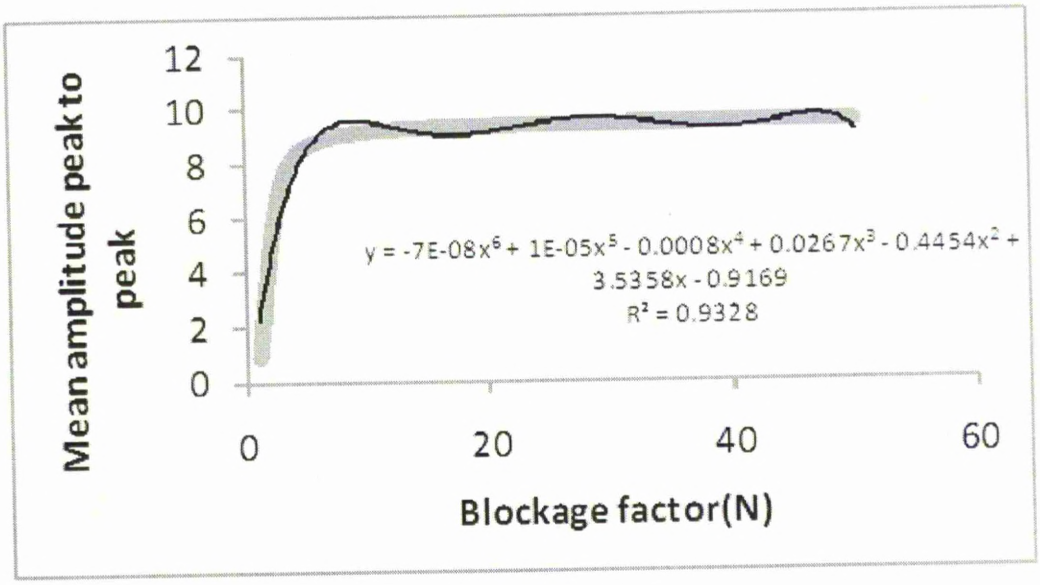
FIGURE 5.11: The relations between blockage factor and calculated ICP parameters; (a) Change in MAD over close duration and (b) Mean peak to peak amplitude of ICP over close duration, black line present the line best fit.

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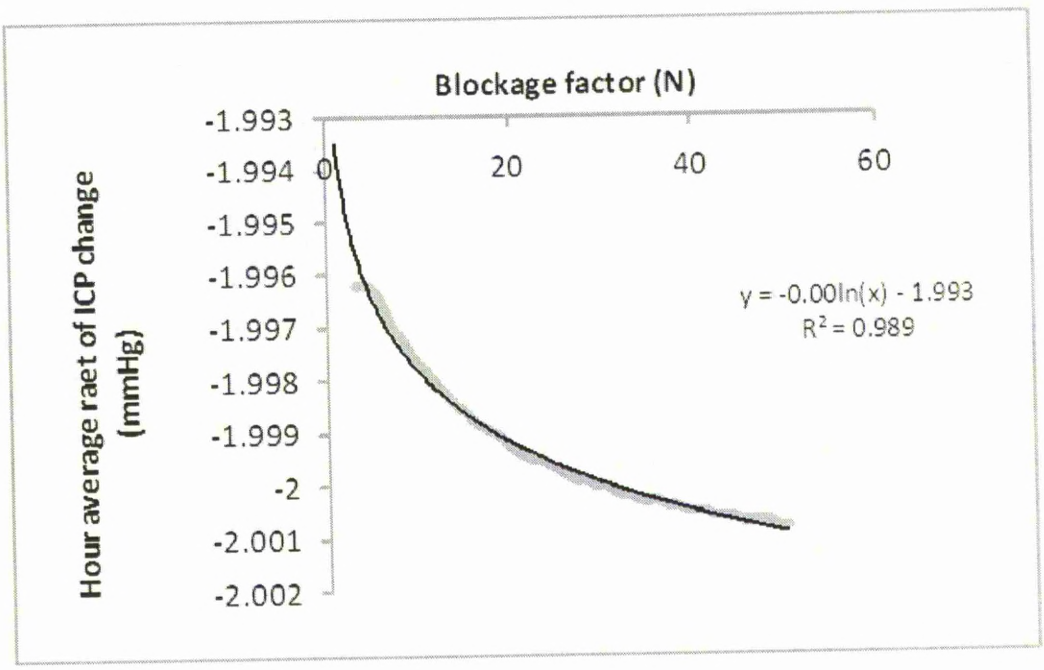


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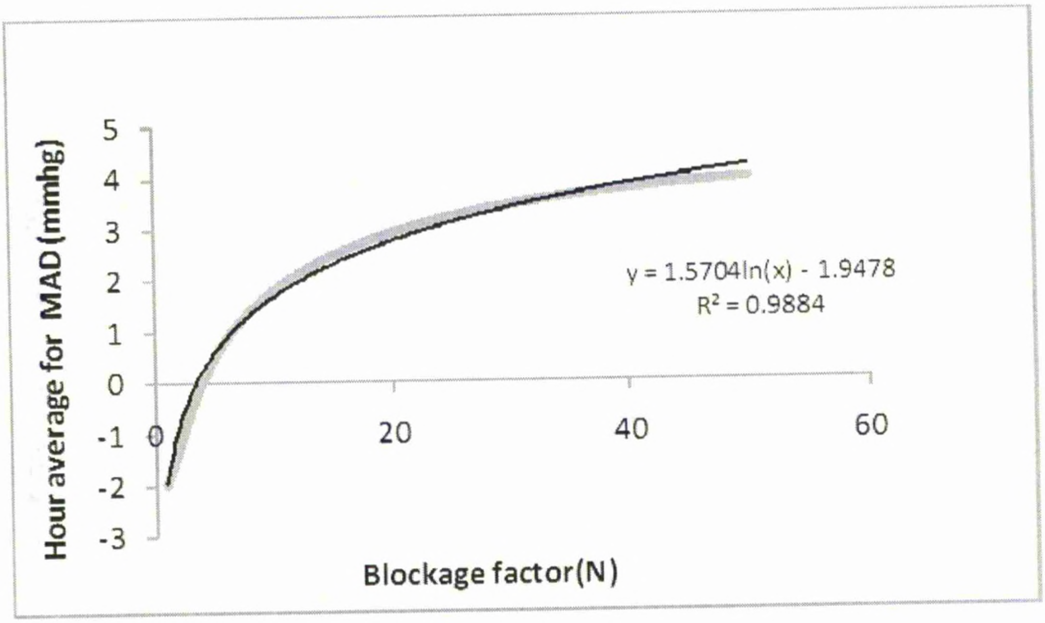
FIGURE 5.12: The relations between blockage factor and calculated ICP parameters; (a) Mean peak to peak amplitude of ICP over open duration and (b) Hourly average rate of ICP change over open duration, black line present the line best fit.

TABLE 5.3: The relations between selected parameters and the blockage factor (N)

| Parameters | Model |
|---|---|
| Change in volume over open duration | $0.027ln(N) + 0.1184$ |
| Rate of ICP change over open duration | $0.3480ln(N) - 2.5941$ |
| Rate of ICP change over closed duration | $0.007ln(N) - 0.0074$ |
| MAD over open duration | 5.6412ln(N)+25.269 |
| MAD over closed duration | 9.342ln(N)+0.3087 |
| mean peak-to-peak amplitude over open duration | $0.3480ln(N) - 2.5941$ |
| mean peak-to-peak amplitude over closed duration | $1.1416ln(N) + 0.0973$ |
| mean peak-to-peak amplitude over closed duration | $1.1416ln(N) + 0.0973$ |

blockage. As a result, the implanted code would used these values for hourly or daily detecting valve blockage instead of using slots values.

The values of the parameters were calculated form the initial period of shunt implant would act as reference points on which a decision is made to identify the blockage. The estimated reference parameters would be calculated by implanted embedded code based on open duration, ICP and the valve resistance. As a result of using mechatronic valve, microcontroller and ICP sensor, assessing performance of self shunt diagnosis and blockage detection is possible by using such methods.

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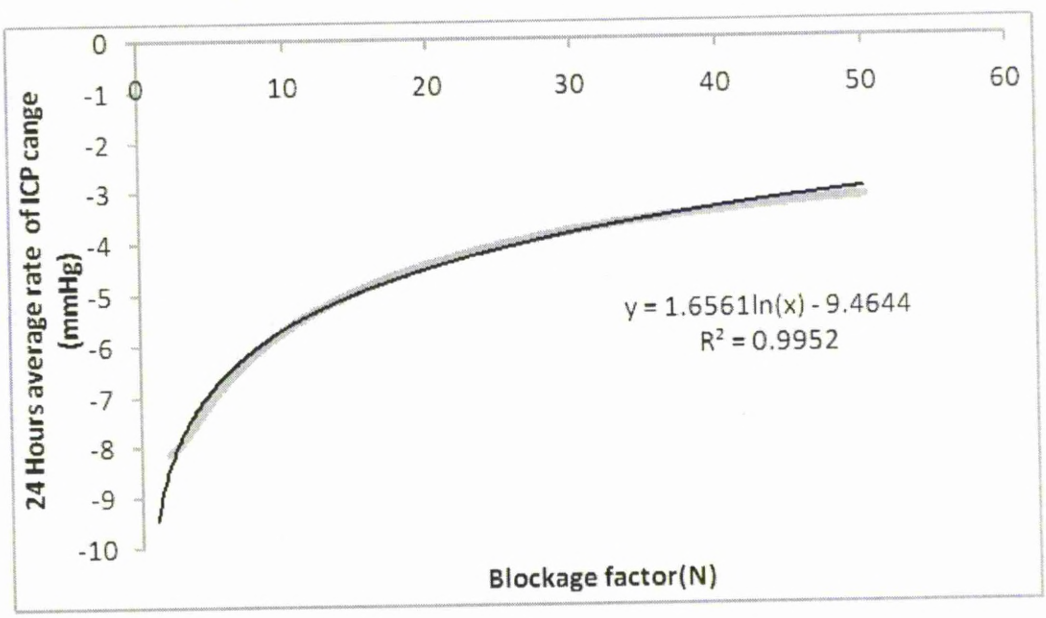


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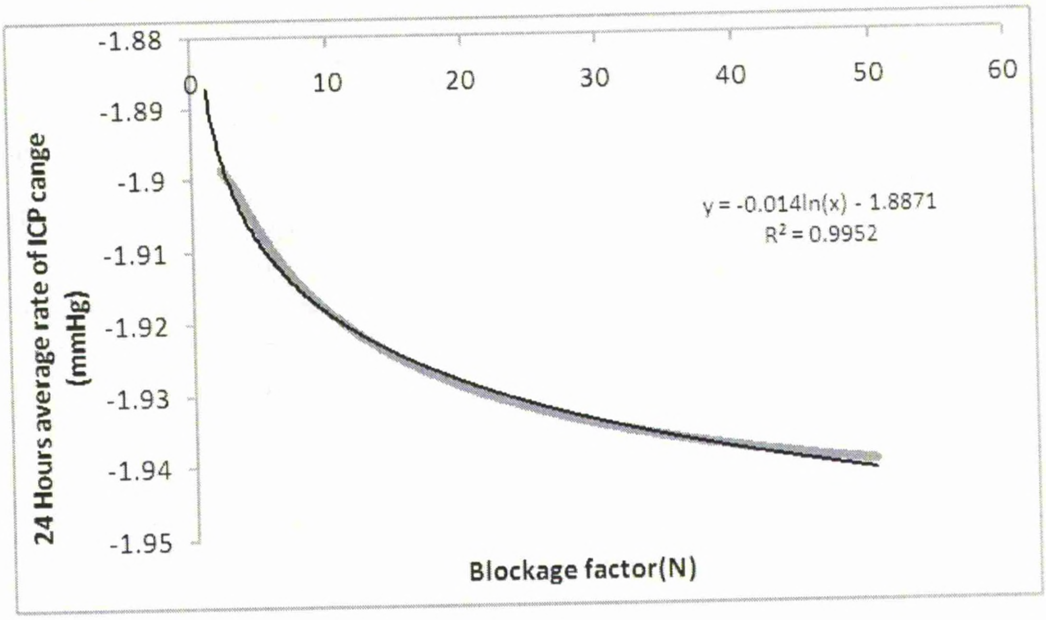
FIGURE 5.13: The relations between blockage factor and calculated ICP parameters; (a)Hourly average of MAD change over open duration and (b) 24 hours average rate of ICP change over open duration, black line present the line best fit.

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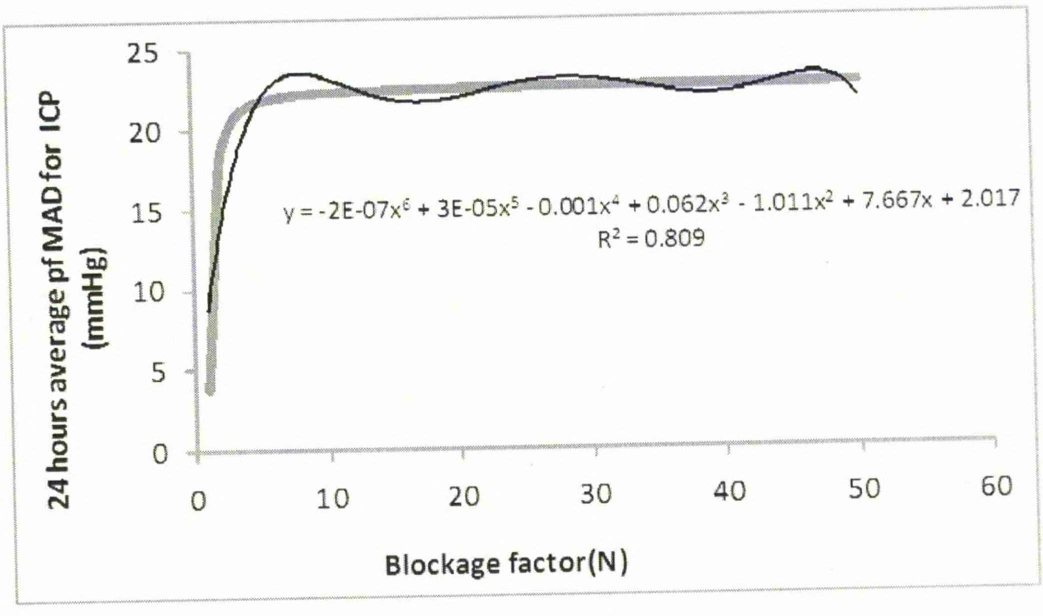



(b)

FIGURE 5.14: The relations between blockage factor and calculated ICP parameters; (a) 24 hours average rate of ICP change over close duration and (b) 24 hours average change in MAD over open duration, black line present the line best fit.

To make the proposed method more accurate, simple modelling has revealed the ability of calculating a blockage factor without using any implanted reference parameters. The intracranial dynamics has been simulated at different open durations ($d$ = 5, 10, 15, 20 and 25 minutes) and different blockage resistance ($N$ = 0, 1, 2, ..., 49) to derive such relation. The relation between $\frac{\Delta ICP}{\Delta t}$ with blockage factor ($N$) is investigated and it was assumed to be linear at fixed open duration ($d$),

$$\frac{\Delta ICP}{\Delta t} = AN + B \tag{5.23}$$

where $A$ and $B$ are constants depending on the value of open duration.

Empirical relations of $A$ and $B$ with the open duration ($d$) are determined,

$$A = -3 \times 10^{-}5d^3 + 0.0015d^2 - 0.0231d + 0.1267 \tag{5.24}$$

$$B = 0.0006d^3 - 0.0266d^2 + 0.3408d - 0.5687 \tag{5.25}$$

These empirical relations would enable the embedded code to detect the blockage and estimated its value. Figure 5.15 and Figure 5.16 show the relations between open duration length and the values of A and B parameters.

A graphical user interface to simulate various shunt malfunctions was designed and developed as shown in Appendix E.

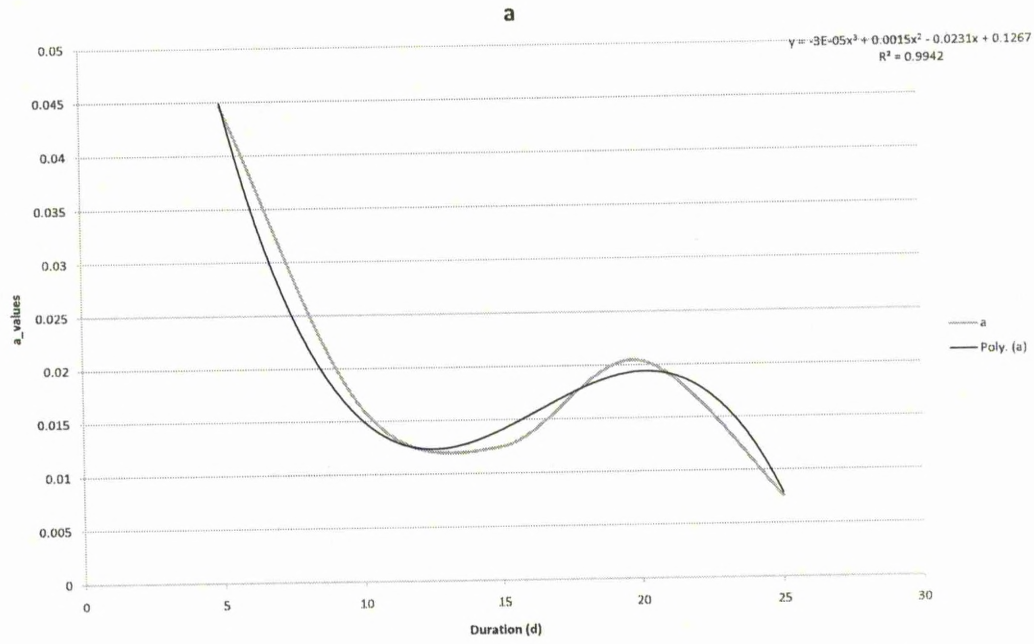



FIGURE 5.15: The relation between open duration length and the value of parameter A, black line present the line best fit.

## 5.5 Conclusions

In this work, a new methodology to study the relationships of the ICP derived parameters such as rate of ICP change, change in volume over time, pulse amplitude pressure (ICPpp), power of ICP signals, drift index of ICP sensor and with shunt malfunctions and complications is proposed. Such relations have been used to illustrate the techniques of shunt self diagnosing . Analysis of the ICP signals has been done to derive such parameters. Further study has been done to derive some parameters for early detection of breakage or dislocation of the ICP sensor. Simple modelling of these relations can help the embedded code to predict the reference values of such parameters which would be used in detecting any malfunctions. A blockage factor ($N$) was derived and modelled and it is found that it can be used as one of the early fault detection parameters. The out come of this study are shunt malfunctions parameters and initial method for early fault

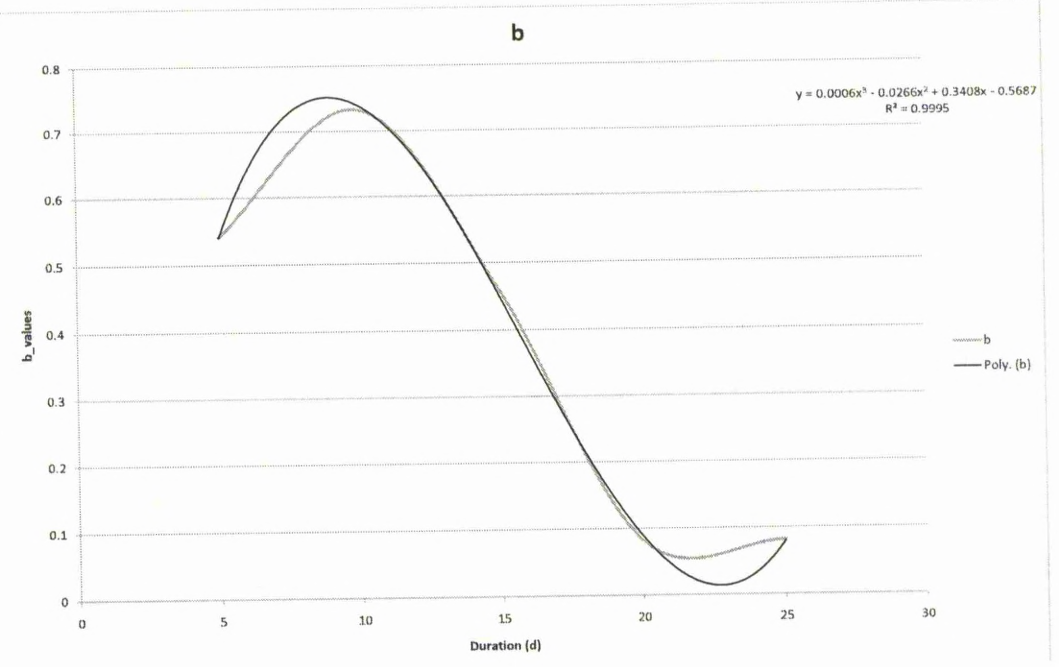



FIGURE 5.16: The relation between open duration length and the value of parameter B, black line present the line best fit.

detection. This outcome will be used in self diagnosis system which is covered in Chapter 6. Whereas some of the selected parameters (mean ICP, MAD and flow rate) were used as input variables in the proposed fuzzy logic controller system. It can be concluded that abstract ICP data is not enough to improve the treatment unless it is analysed and valuable parameters were extracted. It seems to suggest that even though the shunt is implanted inside the body, it is possible to early detect any faults, blockage or complications by using such techniques.

# Chapter 6

# Fuzzy Logic Based Fault Detection and Diagnosis[4]

## 6.1 Introduction

A method was proposed in Chapter 5 for deriving and selecting shunt faults detection parameters that would used for early detecting and identification of various shunt malfunctions. In addition, a method for initial faults recognition was proposed based on using such parameters. The outcome of this method was a diagnosis statement which includes these parameters as well as the result of initial diagnosis for all valve schedule slots to reflect the status of implanted shunt components.

One of the main aims of this study is to find a suitable method for self diagnosis of the implanted shunting system based on the wirelessly received diagnosis statement from implanted shunt. In addition, one of the main functions of the mechatronic shunting software is shunt diagnosis and faults detection.

Today, artificial intelligence technology (e.g. fuzzy logic) is increasingly deployed for faults diagnosis. Fuzzy logic is a rule-based system that successfully combines

[4]Part of this chapter has been published under the title "Fuzzy Logic Based Fault Detection and Diagnosis of a Mechatronic Hydrocephalus Shunting System", in 1st International Conference on Applied Bionics and Biomechanics (ICABB-2010), 14-16, 2010, Venice, Italy.

fuzzy set theory with the inference capability of human beings. It makes use of the knowledge of experts which is possible through its transformation into linguistic terms. The accuracy of the formulation can be determined during the testing of the system or during real-time working by observation. This feature provides major flexibility for fuzzy logic.

Fuzzy logic has several advantages like less modeling complexity and ability to translate human reasoning using linguistic variables. This makes it possible to take into account the uncertainties and nonlinearities otherwise very difficult to model mathematically. In the last several years there has been significant growth in the number of fuzzy logic applications especially in faults detection and system diagnosis.

Fuzzy logic has been effectively used in the engineering studies, such as detecting faults in internal combustion engines and motors [123], [95], [119]. It also has been widely used in medical applications where it works as assistant system that supports the physician to identify malfunctions, e.g. malnourished patient [119]. The need for such system in the medical field necessarily arises from the fact that the late fault detection could be life threatening. As far as the author's knowledge, fuzzy logic was not implemented in fault detection of implanted device inside the body of the patient.

An initial conventional method for self diagnosis of implanted shunt components was proposed in Chapter 5. Such method has been selected based on the difficulty of used high level languages or applications inside the implanted microcontroller due to the limitations of such microcontroller. This conventional method has some disadvantages. A value just below the threshold is not considered as a fault while some value just above the threshold will be considered as a fault. This can also lead to missing detected of some faults. In addition, The conventional method does not consider a smooth transition between the faulty and the no fault condition. This motivate the author to find out an accuracy method that would used the outcome of previouse method to improve the performance of shunting system.

To solve the drawbacks of the previous method, a complementary fuzzy-logic-based fault diagnosis system was developed to diagnose the faults in hydrocephalus shunting system. Numerical simulations have been performed using Simulink model that reproduces intracranial hydrodynamics of acute hydrocephalus patients using historical ICP data. Various expected shunt faults have been modelled using Simulink. The model of a patient with a faulty shunting system was interfaced with the fuzzy logic model in Simulink. A fuzzy logic controller system for detecting and classifying shunt faults was designed and implemented in Matlab. In addition, the fuzzy logic controller is interfaced with acute hydrocephalus patient model using Simulink. Finally, fuzzy logic controller was tested in real time environment. The fuzzy logic classifier model was developed using MATLAB. The accuracy of the fuzzy logic classifier for different fault conditions was determined. Using the developed fault diagnosis system, six general faults were successfully diagnosed. These faults are diagnosed based on the membership functions and rule base developed by the fuzzy logic system.

This chapter demonstrates the use of fuzzy logic as an extension to analytical system to enhance the overall performance of the mechatronic shunting system. The decision of whether a fault has occurred or not? is upgraded to what is that fault? at the output. More importantly, simulation results demonstrate how fuzzy logic is advantageous over the conventional method by being more informative regarding the fault condition and being more sensitive to faults.

## 6.2 Methods and Experimental Work

A Simulink set-up was constructed in order to build the rule base of the shunt faults diagnosis system. It also served to detect the faults in real-time while the model of shunted patient was running under various faults. In addition, such set-up can be utilised as a dynamic environment to evaluate the performance of the fuzzy logic fault diagnosis system. The Simulink set-up consists of a hydrocephalus patient model, a data pre-processing model and fuzzy logic controller, as illustrated in Figure 6.1. The patient model is made up of an intracranial hydrodynamics model of hydrocephalus patient, a simulated valve, ICP sensor, flowmeter, and fault models.

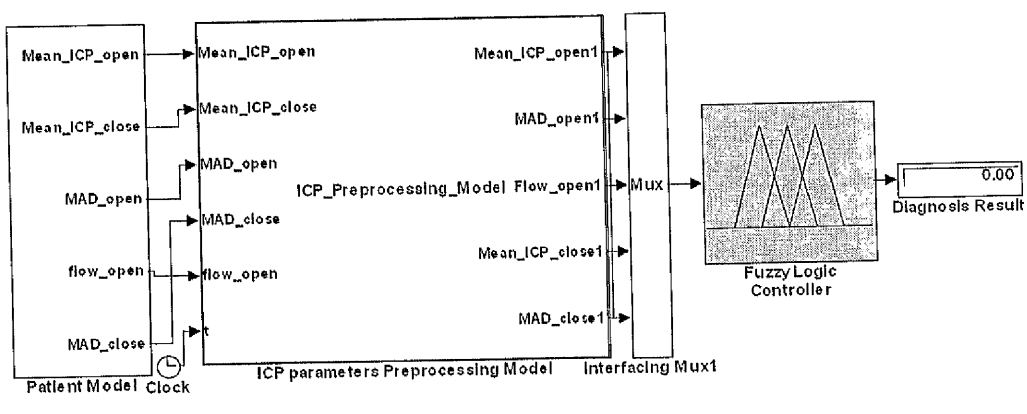



FIGURE 6.1: A block diagram of the Simulink set-up for the self diagnosis system.

### 6.2.1 Intracranial Hydrodynamics and Fault Modelling

Numerical simulations have been performed using a model that reproduces intracranial hydrodynamics of acute hydrocephalus patients using historical ICP data [75]. This model is illustrated in Figure 6.2 and was used as a dynamic environment to reflect the effect of adding a mechatronic valve to the intracranial hydrodynamics. A valve schedule is used to control the opening and closing of this valve.

Early diagnosis of shunt disfunction is not always straightforward. Leading symptoms such as headache, vomiting and drowsiness may all overlap with a variety of other, more common conditions seen in paediatric practice. Therefore, most common shunt faults, as described below, and their effect on the intracranial hydrodynamics were modelled where they were randomly incorporated into the intracranial hydrodynamics model.

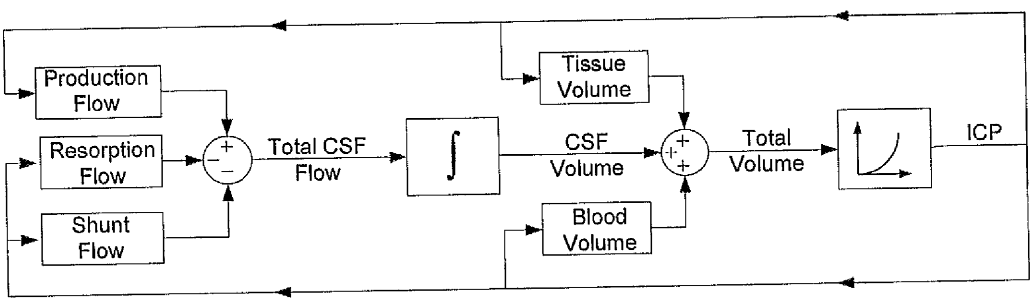



FIGURE 6.2: Hydrocephalus patient model [75].

1. Currently, valve blockage is one of the most effected fault in shunt performance. Detection of shunt blockage is vital as delay in diagnosis can lead to coning and death [7]. Thus, Momani model [75] is modified and used to simulate different degrees of valve blockage by manipulating the resistance of the valve. The blockage factor N was used as a blockage parameter to select the percentage of blockage. In addition, the values of this parameter were selected randomly in this simulation. The dramatically changing in ICP signals due to blockage factor was used to evaluate the performance of the proposed fuzzy logic approach in case of detecting such fault.

2. Disconnection of the shunt is considered the second most common cause of shunt failure. Disconnection may occur at any site of connection along

the course of the tubing [7]. The disconnection considered here is usually related to improper technique (loose ligature) or excessive strain along the shunt tube between two points of fixation. It is simulated by introducing abrupt change in ICP readings, leading to zero ICP values. As a result, ICP signals were missed due to such fault and this simulation used to evaluate the proposed fault detection method.

3. Technical complications occur while using ICP sensor in monitoring ICP such as breakage, dislocation or failure of ICP recording for unknown reasons. These problems also would affect the performance of the shunting system. To increase the efficiency of shunting system and improve treatment, self diagnosis of the implanted pressure sensor has been studied, where a Simulink model for hydrocephalus patient with sensor dislocation problem has been used to illustrate such problem.

4. Other shunt malfunctions also have been studied and simulated such as valve leakage and flowmeter faults.

All previous shunt faults and their effect on the intracranial pressure were simulated and illustrated in Figures 6.7- 6.10.

### 6.2.2 Fuzzy Logic Controller Design

Fuzzy logic is a rule-based system that successfully combines fuzzy set theory with the inference capability of human beings. As rules, linguistic terms are used and are modeled through membership functions that represent simulation of the comprehension of an expert. Membership functions give the scaled value of definite number values that are defined by linguistic labels. Rules are defined such as IF (condition) THEN (result). The conditions and results are linguistic terms that represent the input and output variables respectively. A rule base of the fuzzy logic classifier consists of many rules. It is used to obtain a definite output value according to the input value. The simplest fuzzy logic controller is mainly consisting of input variables, fuzzifier unit, interface unite, defuzification unit, output variables and knowledge base [66].

A fuzzy logic fault diagnosis system was implemented to detect any faults in the shunting system. Figure 6.3 illustrates the flow of data through the fuzzy logic fault diagnosis system.

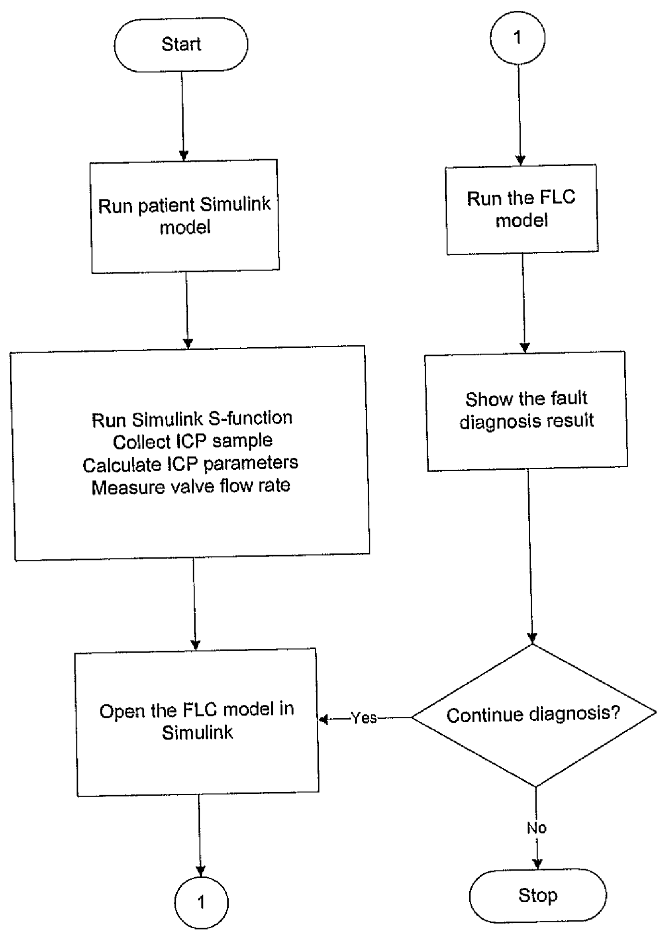



FIGURE 6.3: A flow chart of the fuzzy logic fault diagnosis system.

Many parameters which are deflected from normal (i.e. no fault) values were monitored while the Simulink was running. In addition, the fuzzy logic fault diagnosis system, connected to the hydrocephalus interactive patient models, was working on detecting the faults in real-time. In this study, the number of detectable faults were increased as well as the reliability of the detection system were improved by measuring more than one intracranial pressure parameters (mean ICP, mean absolute deviation) and as well as the valve flow rate which are generated from patient Simulink model based on valve and ICP sensor schedule. These parameters have been optimization in previous research and it was noticed that there is a strong relation between these parameters and the effect of various shunt faults over their behaviour. The results of the numerical simulation were used to create a rule base. The developed fuzzy logic classifier model was designed in MATLAB fuzzy inference system editor.

Figure 6.4 presents a flow chart of the fuzzy logic classifier design. The most important feature in the stage of fuzzy logic classifier design is selecting membership functions that represent input and output parameters in a way that can absolutely define the system. The proposed fuzzy logic system consists of five inputs and seven outputs. The selected input variables were Mean ICP, Mean Absolute Deviation of ICP (MAD), and flow rate at opening and closing times of the valve. Each input variable consists of five membership functions. These functions are in the form of very low, low, normal, high, and very high. Each membership function of the output variable indicates one or more faults. For example, the rule base was generated in case of valve disconnection fault is: IF mean ICP after valve open is very high, AND MAD after valve open is very high, AND valve flow unavailable, AND mean ICP before valve closed is very high, AND MAD before valve closed is very high). Based on the values of the selected parameters, the rule base of shunt diagnosis system is generated and illustrated in Table 6.1.

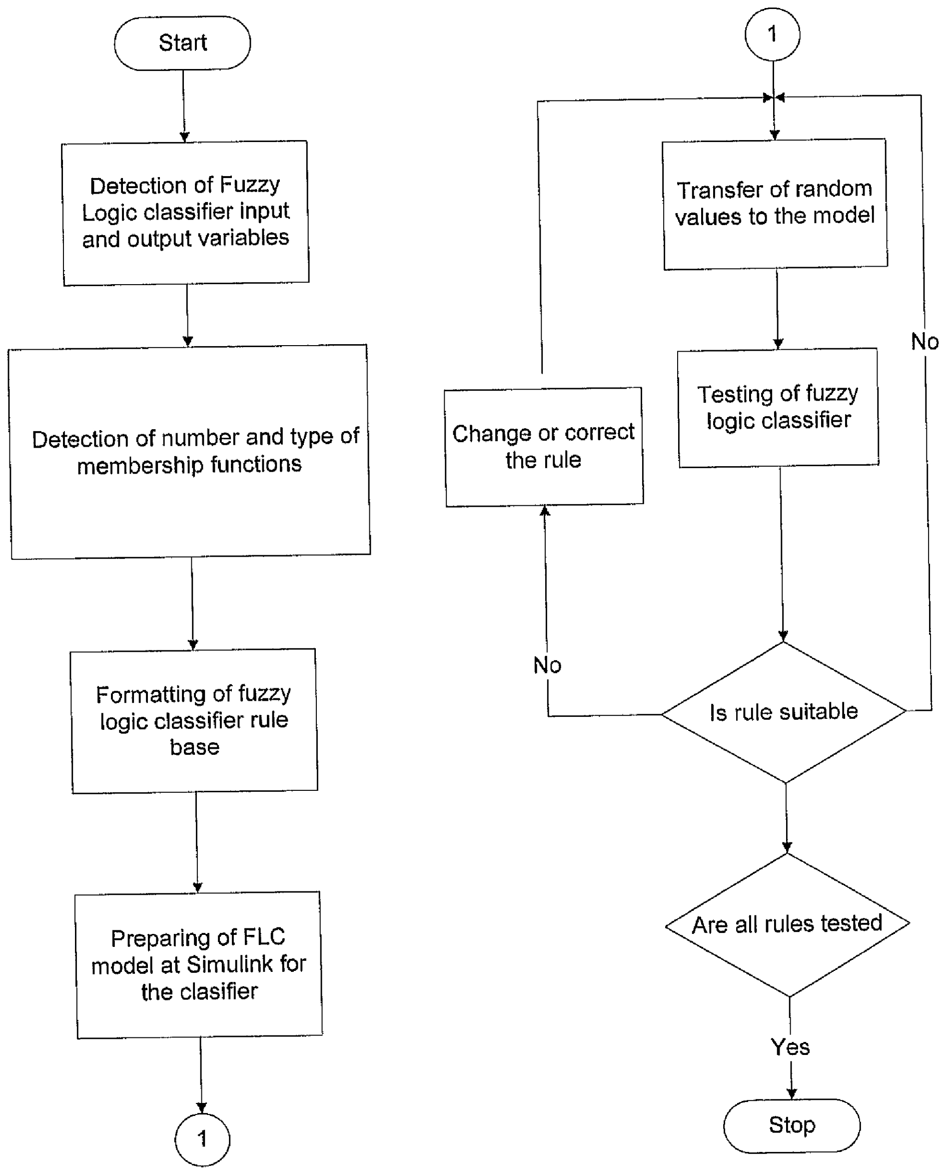



FIGURE 6.4: A flow chart of fuzzy logic classifier design.

The rules can also be seen from the rule viewer using the fuzzy logic toolbox in MATLAB software. For example, when mean ICP when valve open, MAD when valve open, mean flow when valve open, mean ICP when valve closed and MAD

TABLE 6.1: Rule-base of shunt fault diagnosis using fuzzy logic controller and Simulink patient model.

| Shunt state | Mean ICP before open the valve | Mean ICP before close the valve | Mean valve flow | MAD before open the valve | Mean ICP before close the valve |
|---|---|---|---|---|---|
| No fault | Normal | Normal | Normal | Normal | Normal |
| Flowmeter fail | Normal | Normal | Unavailable | Normal | Normal |
| Sensor dislocation | Unavailable | Unavailable | Normal | Unavailable | Unavailable |
| Valve partially blockage | High | High | Low | High | High |
| Full blockage | Very high | Very high | Very low | Very high | Very high |
| Valve disconnection | Very high | Very high | Unavailable | Very high | Very high |
| Shunt fault | Unavailable | Unavailable | Unavailable | Unavailable | Unavailable |

when valve closed are in normal ranges, the diagnosis result is far away from both the upper and medium thresholds (almost at the lower) and hence, has no fault in the shunt. On the other hand and when mean ICP when valve open, MAD when valve open, mean flow when valve open, mean ICP when valve closed and MAD when valve closed are in valve blockage ranges, the diagnosis result is the valve is in blockage case. Figures 6.5 and 6.6 show samples of the rule viewer for previous two cases.

### 6.2.3 Numerical Simulations

Initially, the data were acquired from a shunted patient model with no faults. Then, different faults according to Table 6.2 were randomly introduced into the shunt. Then and the intracranial hydrodynamics data was monitored and measured with six different faults for 12 hours. While the patient model was running under different conditions such as no shunt fault, valve blockage, valve disconnection, ICP sensor dislocations and flowmeter fault. Figures 6.7- 6.10 show samples of the effect of the previous faults on the trace of the ICP and valve flow. Figure 6.7 presents the case of no fault, in this case the value of mean ICP is within normal range (0-12mmHg) and the average of flow also within normal

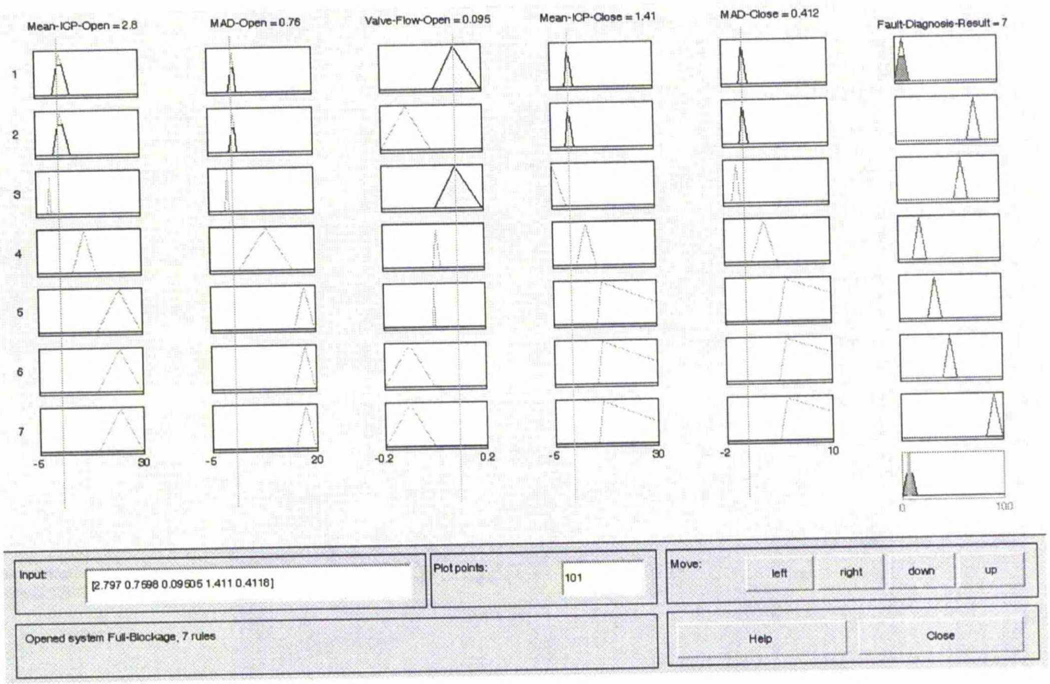



FIGURE 6.5: Test result for no fault

range (Flow=0.03ml/min). Figure 6.8 presents the case of partial valve blockage, in this case the value of mean ICP is rising due to blockage (ICP greater than 15mmHg) and the average of flow also reduced (Flow less than 0.02 ml/min). Figure 6.9 shows the case of valve disconnection, in this case and at the disconnection time the value of mean ICP is rising due to blockage (ICP greater than 15mmHg) and the flow is missing due to valve disconnection (Flow=0 ml/min). Figure 6.10 shows the case of ICP sensor dislocation, in this case the ICP signal is missing due to sensor dislocation(ICP=0 mmHg) at same time the average of valve flow is within normal range.

The next step was transmitting the measured data to the pre-processing model. The pre-processing model is mainly used to extract and optimize the selection parameters from the transmitted data. Samples of ICP and flow readings (600 readings per period) were taken at specific periods (before the scheduled opening and closing time of the valve) and were used in the derivation of the parameters.

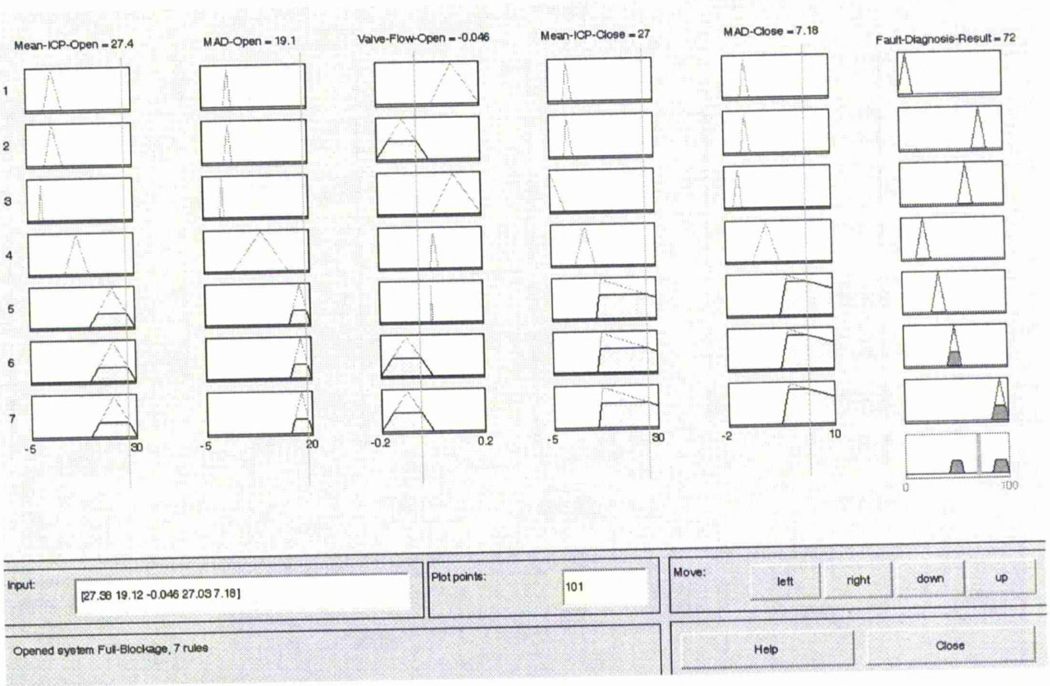



FIGURE 6.6: Test result for full valve blockage.

TABLE 6.2: Hydrocephalus shunt faults taken into consideration.

| ICP behaviour | Probable source of fault |
|---|---|
| ICP signals and flow measurements are normal | No fault |
| ICP increases<br>Flow decreases | Partial valve blockage |
| ICP gradually increases and very high<br>Flow gradually decreases and very low | Full valve blockage |
| ICP suddenly becomes very high<br>Flow becomes zero | Valve disconnection |
| ICP suddenly becomes zero<br>Flow is normal | ICP sensor dislocation |
| ICP is normal<br>Flow becomes zero | Flowmeter fault |
| ICP and flow become zero | Shunt fault |

Simulation run duration was 12 hours, in which 48 samples of intracranial hydrodynamics data were collected based on valve schedule (that opens for 10 minutes every 30 minutes) and used in this test to derive the parameters. Accordingly, these parameters were implemented as input variables for the fuzzy logic controller system.

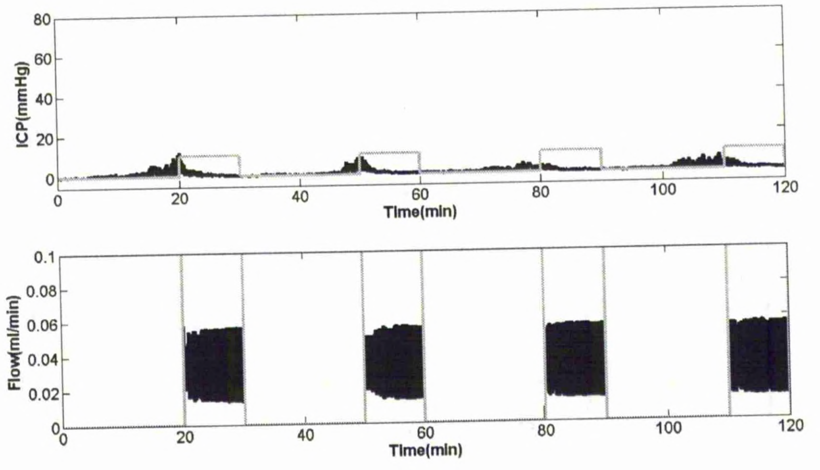



FIGURE 6.7: Simulated ICP and flow traces for normal shunt.

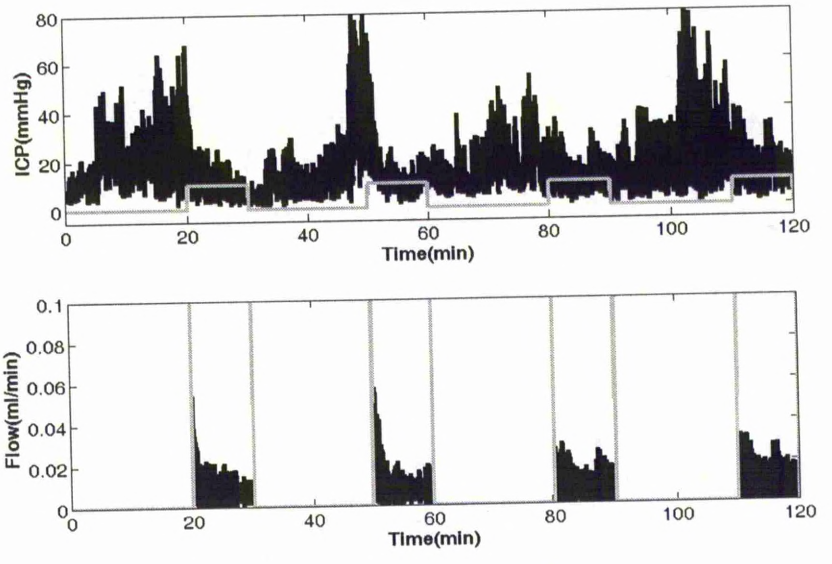



FIGURE 6.8: Simulated ICP and flow traces for Partial shunt blockage.

The derived parameters were used as inputs for the fuzzy logic controller to recognize the faults, and to discriminate between faulty and normal operation. The input and output variables defined for this study and the membership functions are given in Figure 6.11.

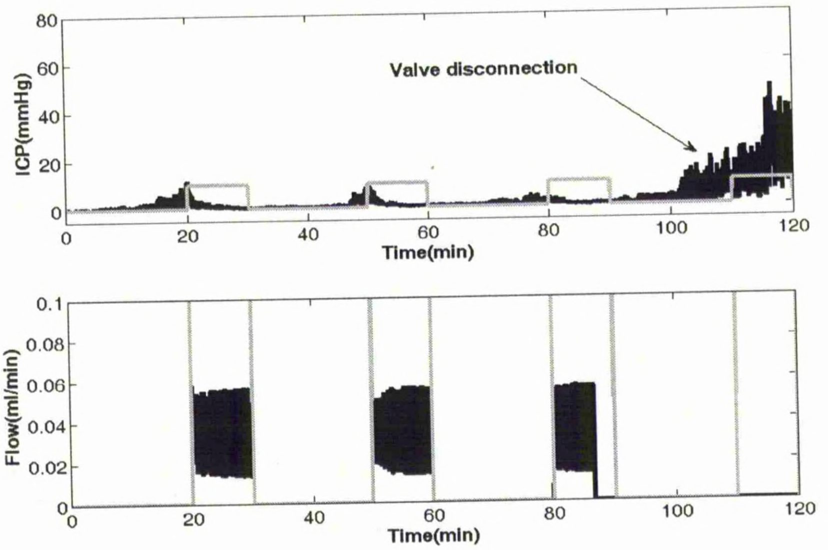



FIGURE 6.9: Simulated ICP and flow traces for valve disconnection .

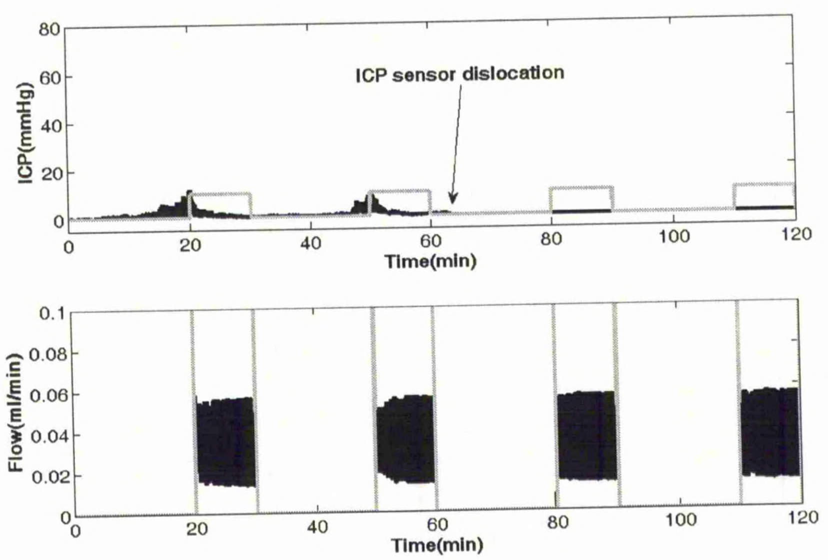



FIGURE 6.10: Simulated ICP and flow traces for ICP sensor dislocation.

## 6.3 Results and Discussion

As a result of this work, a fuzzy-logic-based fault diagnosis system was developed. By using the developed system, various simulated shunt faults were successfully

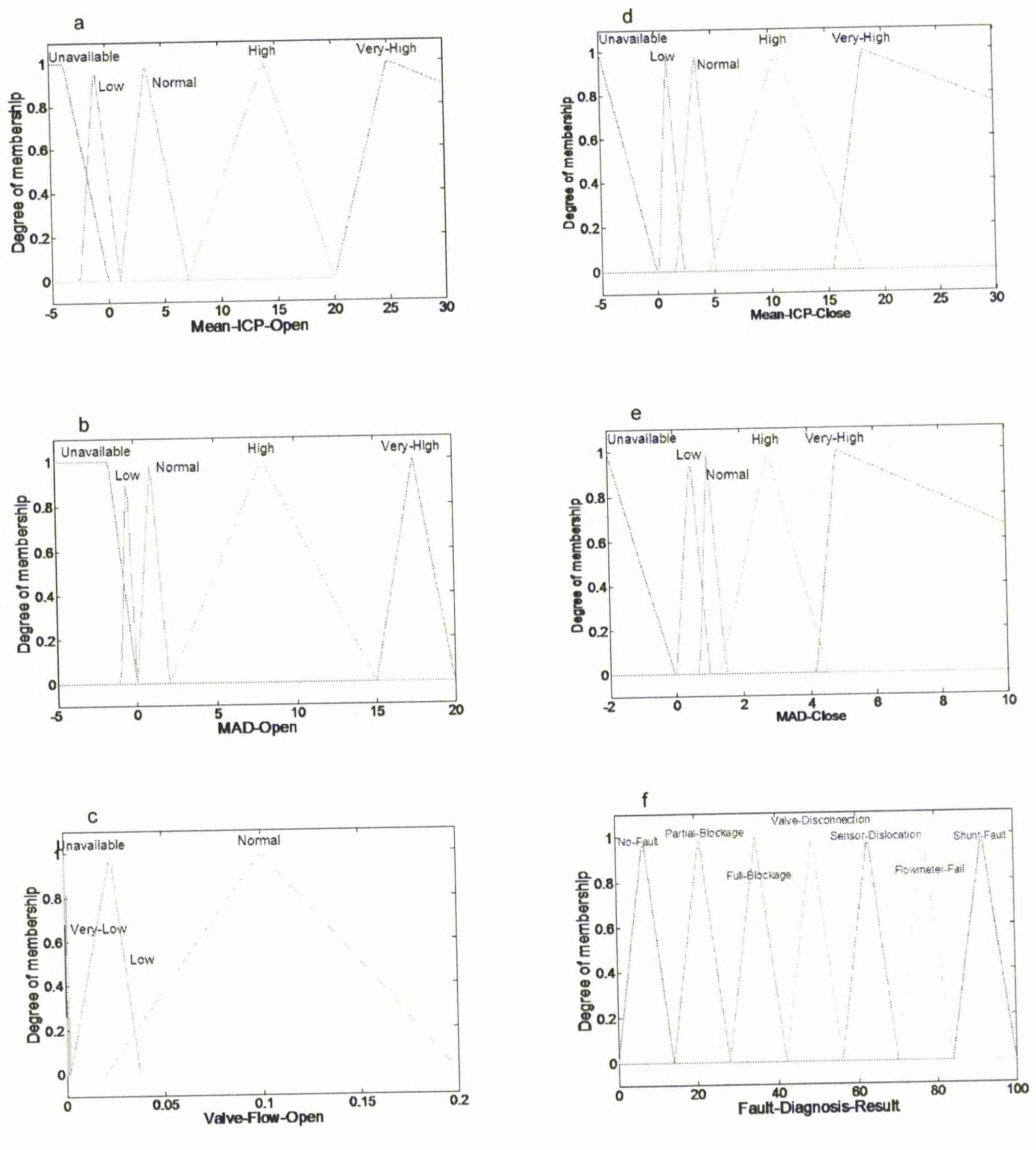



FIGURE 6.11: The input variables, the membership functions of them and the output variables.

detected and classified. A rule-base summerised in Table 6.1 was used to detect and classify various shunting system faults. The fuzzy logic shunt fault diagnosis system was evaluated using the results of numerical simulation. Table 6.3 summarises the results of detecting and classifying various shunt faults. The fuzzy logic classifier was found to classify the faults with more than 85% accuracy. As a result of the characteristics of the selected input variables and the diagnosis criteria is based on five parameters, the accuracy of faults detection and identification is very high. With these features, the system could easily be used as intelligent technique for self diagnosis of hydrocephalus shunting system.

TABLE 6.3: Shunt faults diagnosis results.

| State of shunt | Number of samples | Correct classification | Incorrect classification | Cause of incorrect classification |
|---|---|---|---|---|
| Normal | 48 | 48 | 0 | No fault |
| Valve disconnection | 48 | 48 | 0 | Flowmeter fail |
| Sensor dislocation | 48 | 48 | 0 | Sensor dislocation |
| Flowmeter fail | 48 | 48 | 0 | Partially blocked |
| Partially blocked | 48 | 35 | 13 | Overlapping with full blockage |
| Fully blocked | 48 | 39 | 9 | Overlapping with partial blockage |

## 6.4 Conclusions

Missing the diagnosis of malfunctioning shunt may lead to permanent neurologic injury or death. According to this study, even though the shunt would be implanted inside the body, it is still possible to detect any complication early before the development of symptoms. Fuzzy logic-based approaches (fuzzy logic controllers and fuzzy models) are used effectively to deal with the lack of rule-base methods for system self-diagnosis . With high accuracy of fault detection, fuzzy logic-based strategies have proven to be a good choice for self diagnosis of the proposed mechatronic hydrocephalus shunting system. It would be used to provide important information about shunting system status and would provide information about the transition from no fault to faulty condition.

The advent of such shunting system would give more advanced enhancement to the proposed self-diagnosis method and promising future for such method. With such shunt diagnosis system, the performance of the shunting system would be improved, leading to improved treatment. Furthermore, such technique can be used not just to deal with implanted mechatronic shunt faults but also for any implanted devices inside the human body.

# Chapter 7

# Expert System for Real-time Analysis of Patient Feedback [5]

## 7.1 Introduction

This chapter presents the design and implementation of an expert system that aims to provide a suitable decision for self diagnosis hydrocephalus and shunting system. Such decision would help in diagnosing the hydrocephalus symptoms as well as any shunt malfunction. Any dramatic change in ICP (high rising or drift) that makes ICP abnormal would increase the patient suffering and produce symptoms. In addition, most shunt malfunctions cause various problems and produce symptoms. The symptoms are due to pressure building up within the head or it is over drained.

The patient needs to visit a hospital or meet a consultant every time he/she complains from symptoms for diagnosing. Such symptoms usually occur due to shunt complications that cause suffering for the patient and his family. Since these symptoms (e.g. headache, vomiting, fever) are similar to the symptoms of other medical problems, the hydrocephalus patient would worry every time he/she has

[5] Part of this chapter has been published under the title "An Expert System for Hydrocephalus Patient Feedback", in 32nd Annual International IEEE EMBC Conference, Aug 31 - Sep 4, 2010, Buenos Aires Sheraton Hotel, Buenos Aires, Argentina.

such symptoms. In this case, the patient will only be assured if he/she contacted a physician. The diagnosis of such malfunctions can be both difficult and perplexing even for the experienced clinician.

At present, follow-up of shunted patients varies between neurosurgical centres. In some, the patient is seen annually and more frequently if his/her management proves more difficult. Others adopt a more open form of follow-up where patients are only seen if they develop problems [56]. The methods used to date have been based on clinical presentation of shunt malfunctions, clinical data, imaging techniques and evaluation of valve function in mechanical terms. All these systems fail to pick up the daily variations in the patient's condition, the build-up of symptoms prior to deteriorations and do not reflect the differences needed in monitoring individual patients.

Currently, a mechatronic valve with control software is under investigation and will be a future solution for most of current shunt problems. The control software will work on modifying the opening/closing times of the implanted valve based on many inputs. One of the prospective inputs is patient feedback. In addition, the system uses ICP data that would collect from implanted sensor to monitor the health of the patient as well as the shunt.

This motivated the author to develop an automated tool that diagnoses patient symptoms at any time. Where the hydrocephalus patient or a caregiver can play a vital role in managing hydrocephalus. As a result, advice is given to the patient either to contact the physician or assure him/her that the cause of the symptoms is not due to shunt complications.

As the use of the Internet continues to grow, it can be a very useful tool in promoting a mutually beneficial discussion between the physician and hydrocephalus patient about symptoms and treatment. In addition such discussion can help improve patient' knowledge and understanding. In this case, online self diagnosis for hydrocephalus and shunt would be a revolution for hydrocephalus patients. That would lead to a reduction in the inconvenience of these patients by reducing the number of visits to the physician as well as optimising the patients time and treatment cost.

Expert systems, or knowledge-based systems, are a branch of artificial intelligence. An expert system is a computer program that attempts to replicate the reasoning processes of experts and can make decisions and recommendations or perform tasks based on user input. Expert systems derive their input for decision-making from prompts at the user interface, or from data files stored on the computer. The knowledge base upon which the input is matched is generally represented by a series of IF/THEN statements, called production rules, which are written with the domain expert to approximate the expert's reasoning.

Expert systems are used in various medical applications such as pulmonary medicine [55] and the prescription of drugs (e.g. MYCIN [63]). Furthermore, medical expert systems can be applied to various tasks such as generating alerts and reminders, diagnostic assistance, treatment planning information retrieval, and image recognition and interpretation [40]. To the best of the author's knowledge, expert systems have not yet been applied to hydrocephalus management and treatment.

Treatment represents the application of different health care interventions for the cure or reduction of disease-related symptoms. Treatment satisfaction is defined as the individual's rating of important attributes of the process and outcomes of his/her treatment experience. Treatment satisfaction focuses on one aspect of satisfaction with medical care [87], [115], [70] and involves the interaction of expectations, preferences, and satisfaction with medical treatment. Whereas health status instruments measure the outcomes of treatment (for example, biological/physiological, symptoms, functioning, and well being), treatment satisfaction scales assess the level of satisfaction with these health status outcomes.

The design of a mechatronic shunting system is under investigation and illustrated in previous chapters [72]. Such system consist of two subsystems; implantable and external (smartphone) subsystems. By using this system and utilising the ability of the patient to measure his/her satisfaction with the level of treatment, a real-time patient feedback system would be an important part of personalised management of hydrocephalus and self diagnosis of any shunt malfunction. In addition, such system would hold promise for reducing the need for shunt revision. The proposed method of collecting patient feedback can be either via a smartphone or through any internet browser.

In this work, a questionnaire system for hydrocephalus patient feedback was designed. In addition, the proposed expert system has been implemented in Prolog. The outcomes of such system would personalise the management of hydrocephalus and identify the expected cause of the symptoms.

The development of such expert system will enable the patient to log in either regularly, on desire, or when it is needed. This will permit the system to collect information when well and when not so. All the data will be available to the clinician in any review permitting a more patient-focused method of management. It allows to follow-up patients more closely, alerting him/her to seek medical advice when required. This will provide more enhanced follow-up at a considerably lower cost. The importance of this will be even more in patients living far away from general or paediatric neurosurgical centers.

## 7.2 Methods and Experimental Work

One aspect of care in the hydrocephalus patient is the need for symptom diagnosis. The main function of the shunting system is to keep ICP in equilibrium. To improve the patient treatment, it is important to identify the complications associated with the shunt and, if needed, see out the medical attention necessary to resolve those complications, even if that means undergoing a shunt revision. Both adults and children who suffer from hydrocephalus symptoms must remain constantly aware of the complications that present in case of changing ICP values or shunt fault.

Today, the current protocol of hydrocephalus diagnosis includes the following steps:

1. In case of the symptoms are presented on the patient, the patient or his/her parents contact the physician or visit his/her GP and in this case the patients would be confused between what he has to do; is it better to contact the physician or directly visit the GP,

2. The physician will decide based on the symptoms which will be collected through phone or by clinical presentations if such symptoms are due to hydrocephalus or not,

3. A CT scan could be requested to check before giving the final decision,

4. As a result of CT scan may or may not show any change in ventricle size, particularly if the patient has a history of slit-like ventricles, the physician would request ICP monitoring for the patient (48 hours) to collect ICP data, analyse it and be assured the symptoms are due to rising/drift of ICP or not,

5. Finally, a shunt revision would be requested in operation room to replace the current shunt by new one.

The main objective of this study is to find an intelligent method by utlising the previous procedures to reduce the patient's suffering, diagnosis time, diagnosis cost and make such procedures more systematic. An expert system was selected to achieve such a goal as detailed below.

### 7.2.1 Questionnaire System

Patient satisfaction is a component of healthcare quality and is increasingly being used to assess medical care. Patient satisfaction is an expression of the gap between the expected and perceived characteristics of a service. Satisfaction is a subjective phenomenon and could be elicited by asking simply how satisfied or not patients may be about the service. However, it has been found that questionnaires that ask patients to rate their care in terms of how satisfied they are tend to elicit very positive ratings that are not sensitive to specific processes that affect overall quality. It is recommended that patients are asked to report on their experiences through specific questions [34].

A questionnaire system has been developed to measure patient satisfaction with its shunt service. Medical knowledge of specialised doctors at Walton Neurological Centre in UK was used to develop this questionnaire system which is currently used in diagnosing the symptoms of hydrocephalus. This questionnaire will help in better understanding the patient's feeling about the shunt. This questionnaire was used as an input to the expert system to improve the understanding of shunt state. In addition, the medical knowledge is utilised for the development of this expert system. This knowledge is clustered to three groups and samples of these groups are shown in Figure 7.1.

The first group of questions covers the clinical symptoms of rising ICP and its effect on the patient. The second group covers positional symptoms and how different

TABLE 7.1: A sample of questionnaire form for hydrocephalus patient feedback.

| **Clinical symptoms(Questions)** | **Patient Answers** |
|---|---|
| Do you have Headache | Yes , No, Sometime |
| Do you have Irritability | Yes , No, Sometime |
| Do you have Nausea | Yes , No, Sometime |
| Do you have Lethargy | Yes , No, Sometime |
| **Positional symptoms (Questions)** | **Patient Answers** |
| Relief by lying down | Yes , No, Sometime |
| Relief by sitting up | Yes , No, Sometime |
| Worsening by lying down | Yes , No, Sometime |
| **Day and night variation in symptoms (Questions)** | **Patient Answers** |
| Worst in the morning | Yes , No, Sometime |
| Worst in the evening | Yes , No, Sometime |
| Worst in the night | Yes , No, Sometime |

postures affect the symptoms that would help in diagnosing the type of fault. In the last group, day and night variation in symptoms are covered to illustrate the effect of different patient states on the symptoms.

### 7.2.2 Shunt Diagnosis System

Based on the answers to the above questions, a set of rules is created where each rule contains an IF part that has the symptoms and a THEN part that has the expected state of the shunting system that should be realised. An inference method (forward reasoning) is used through which rules are selected to be served. A simplified finite state machine comprised of a data structure used to show actions with sequence event for such an expert system has been designed based on shunt complication-symptoms relationship. Due to the variations in symptoms with age, the system will deal with three groups of shunt malfunction symptoms: infant, toddler, and adult hydrocephalus patient symptoms. The patient is asked specific questions about his/her experience with his/her current and past symptoms. The system starts by asking if the patient can give his/her feedback at this moment or not and then enquires whether he/she is complaining from any clinical symptoms. Based on the patient answer, the system will step forward to the next state. Figure 7.1 and 7.2 show a finite state machine for the sequence of the proposed expert system which covers sample of the possibilities of the questionnaire form.

The Win-prolog programming environment was used for developing the patient feedback expert system. The expert system developed in this work consists of a user interface, explanatory facility and knowledge base. The structure of the expert system is shown in Figure 7.3.

The system keeps in memory a fact list, a rule list, and all previous cases that have been manipulated. The patients/caregivers communicate with the system through the user interface which was implemented in Win-prolog. The user interface is represented as a form which displays the questions and the answer options for each question. When the system is started, a main menu is displayed on the screen which asks the user to answer the selected questions by choosing one of the answer options.

Finally, the system informs the state of the shunt, i.e. no shunt problem or there is a problem and identifies such problem. After each patient feedback analysis, the analysis result, the patient feedback, the symptoms and the system decision will be stored in local database. A copy of this information would be sent through mobile communication or internet to the physician. Such a database would be used for future as a learning database for the expert system. By applying specific

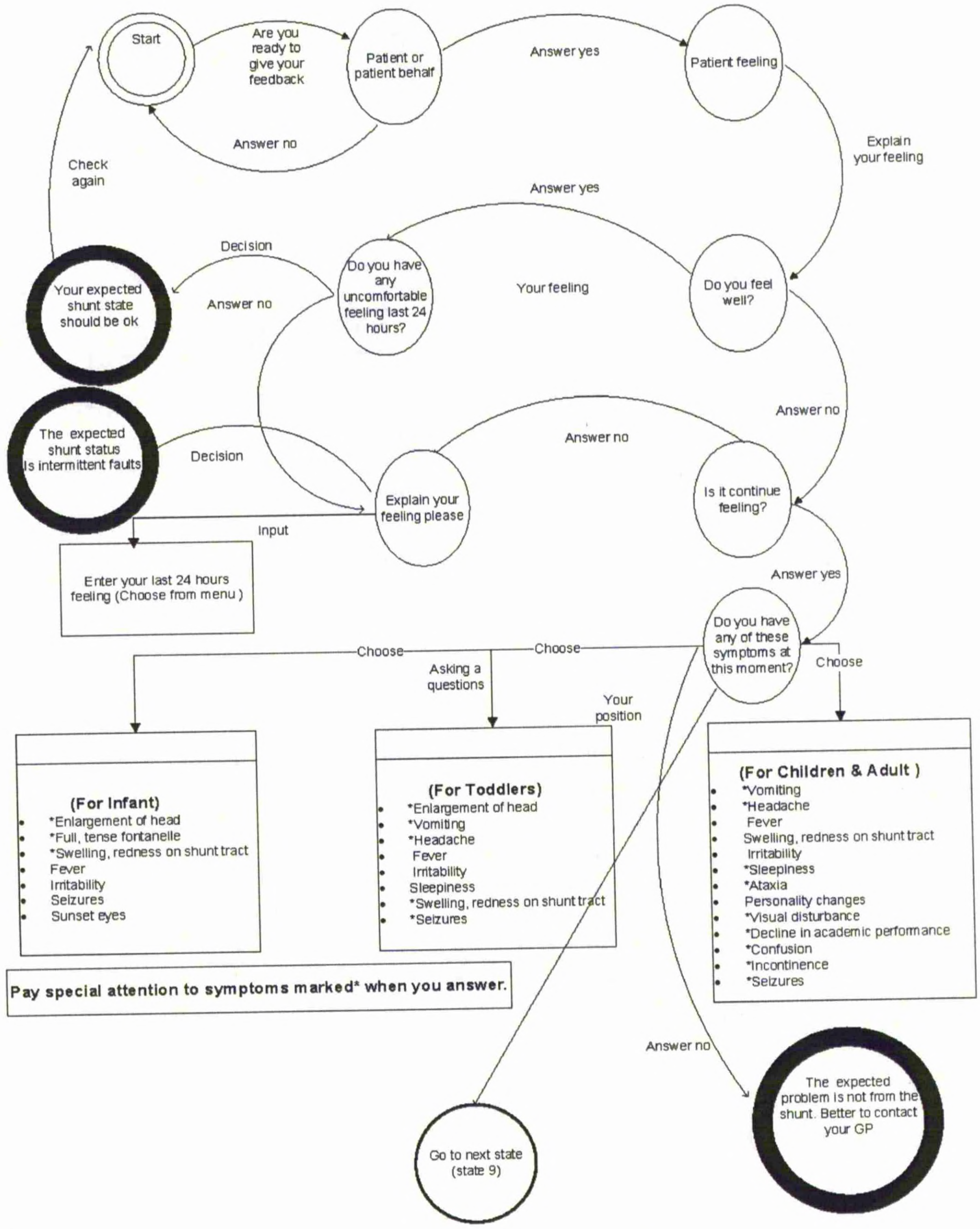



FIGURE 7.1: Finite state machine for hydrocephalus patient feedback expert system (acquisition of patient's feeling and clinical symptoms).

learning algorithm, the system has the ability to search through the database and compare the received symptoms with stored analysis results and decisions to make a quick decision and thus make the system more efficient.

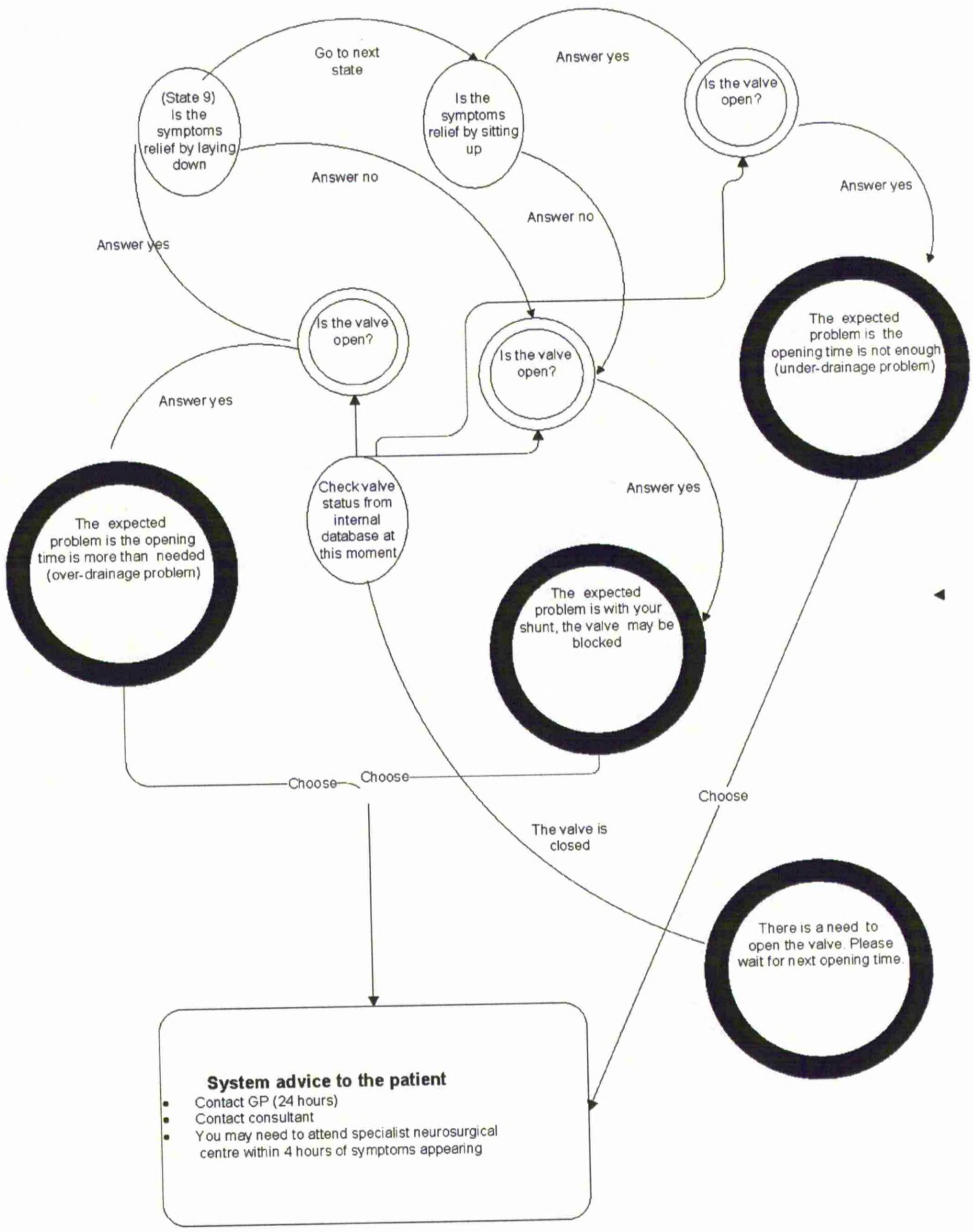



FIGURE 7.2: Finite state machine for hydrocephalus patient feedback expert system (acquisition of the posture, valve state and the final decision).

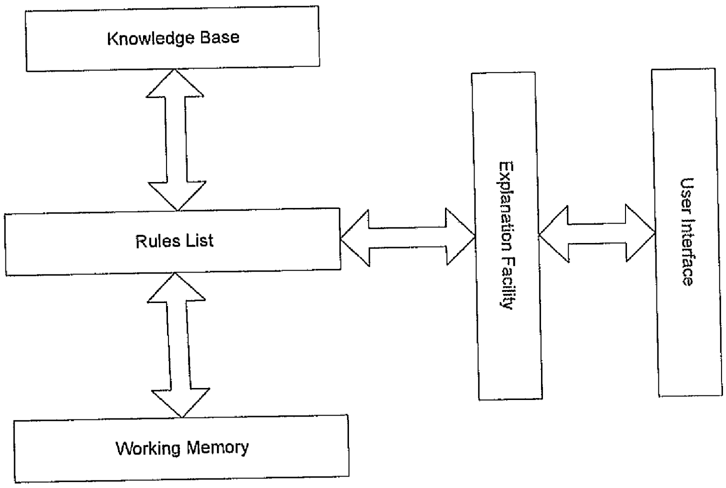



FIGURE 7.3: Structure of the expert system

### 7.2.3 Hydrocephalus Management System

Patients suffering from symptoms while having a mechatronic shunt, will be able to reflect the symptoms by giving their feedback to their shunts through the patient device. This feedback will play a vital role in tuning the management of hydrocephalus. Thus the patient will receive a timely diagnosis and management modification to release the symptoms in almost no time. This avoids the uncomfortable experience of waiting for medical consultation, hospitalisation and diagnosis procedures. When the patient logs his/her feeling of having some sort of symptom, the shunting system will autonomously request a measurement ICP. These readings will be analysed and a decision will be made whether the cause of the symptom is an abnormality in intracranial hydrodynamics. Based on this decision, the shunting system would either modify the schedule according to the new situation and inform the patient the problem has been addressed or just inform the patient that the cause of the symptom was not due to ICP abnormality. The flow chart in Figure 7.4 illustrates this modification based on patient feedback. The advent of such a shunting system would give a more advanced enhancement to the proposed patient feedback expert system.

## 7.3 Results and Discussion

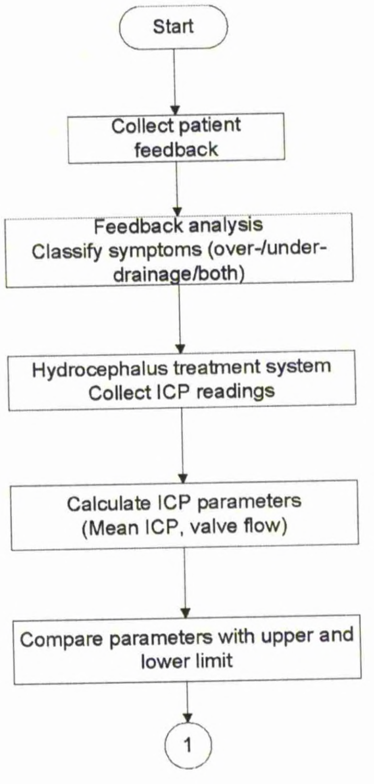
An intelligent automated method for collecting and analysing patient feedback has been investigated. Real-time patient feedback expert system was developed.
By applying such expert system, the patient's details and symptoms are inputs, and the system outputs are the probable diagnosis, recommended treatments or advice. The result of patient feedback analysis system is either that the patient needs to contact the physician or the problem is handled by modifying the opening times of the valve or assure him that the cause of the symptoms is not due to shunt complication. The system has the ability to identify the shunt state, *i.e.* problem existing or not and if yes identify such problem.
Real-time patient satisfaction alerts enable the self diagnosis shunting system to make an accurate and suitable decision. A clinical evaluation of the proposed system is under review based on a medical knowledge of specialised doctor and hydrocephalus patients' feedback. The patients would feed the system with their feedback before they are being diagnosed by a physician. For each patient, the outcome of the system would be compared with the physician diagnosis. Based on this comparison, the performance of the system would be evaluated.

## 7.4 Conclusions

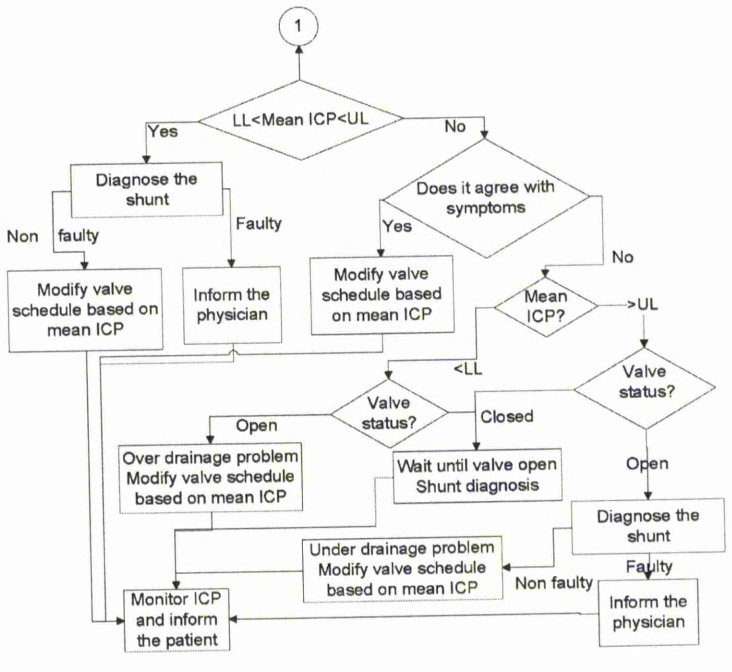
New programmable shunt valves with shunt management and self-diagnosis system hold promise for reducing the need for shunt revision surgery, as the proposed expert system can be autonomous.

The principle work of such system as follow: (1) the patient has symptoms and his/her feeling is not well, (2) the patient request help from the system, (3) the system start collects patient feedback by asking specific questions, (4) based on the stored rules-based and previous experience, the system can diagnose the case and give initial decision, (5) in case of the decision is a hydrocephalus problem, the system inform the treatment system for a suitable action such as valve schedule updating, inform the patient and the physician.

By using the proposed system, the patient can take part in managing the symptoms and diagnosing the shunt. The system constitutes part of an intelligent system of analysing patient feedback. Many believe that medical expert systems have great potential to improve health care by making it more efficient through reducing the time needed to diagnose the problem and reduce the number of human errors. In the case of the proposed system, the hydrocephalus patient has freedom to go anywhere and to do anything without worrying about their symptoms. Some patients would feel happier typing their medical information into their device than discussing it with a human doctor. The cost and time of the patients would be optimised with such system. The disadvantage of using such system is the lack of creative responses that human experts are capable of. Currently there are many expert systems that have made it into clinical use. Many of these are small, but nevertheless make positive contributions to care.




(a)




(b)

FIGURE 7.4: Shunt management modification based on patient feedback); (a) first part, (b) second part.

# Chapter 8

# A Self-Learning Method for Diagnosis of Hydrocephalus Shunting System

## 8.1 Introduction

In this Chapter, a self learning method is proposed that can search for a learning information by inputting variables such as time, date, faults type and more significantly for this study the intracranial pressure(ICP) and flow measurement parameters. In this method, a daily report would be archived in hydrocephalus patient database which includes important ICP and flow parameters such as mean ICP, mean absolute deviation for ICP, change in mean ICP over time and flow measurement, as well as the results of daily shunt diagnosis which was explained in Chapter 6 with the corresponding date and time. The requested information would be analysed to detect any patterns and trends in the previous parameters with times. Such patterns and trends would give a full meaning for current ICP and shunt status.

Intracranial pressure data allows the management of hydrocephalus by objective criteria. This is particularly important because many, and perhaps all, medical and surgical measures for the treatment of intracranial hypertension have significant potential adverse consequences [81]-[22]. Thus, ICP monitoring allows the judicious use of interventions such as ICP signal information, implanted shunt diagnosis information and hydrocephalus management information. This may avoid potentially harmful and overly aggressive treatment such as regular shunt revision and invasive ICP monitoring method. Long-term monitoring of intracranial pressure (ICP) is limited by the lack of an implantable sensor with low drift as well as the power needed for the implanted components. In this case, short period of time has been used to collect small samples of ICP readings. One of the main objectives of this work is to optimise such sample as explained below to be more efficient in management and treatment of hydrocephalus, as well as diagnosis of shunting system.

The work has been done in Chapter 5 by deriving important ICP parameters that would play a vital role in management and treatment of hydrocephalus also in diagnosing shunting system. One of the main challenges, for hydrocephalus researchers as well as for physician or consultant to manage the hydrocephalus and to diagnose the shunt malfunction, is lack of ICP data. To deal with such problem and to build a useful hydrocephalus database, ICP data, patient information and hydrocephalus information are required by using a monitoring method which mainly provides such important information. Based on the designing of the proposed shunting system, this information would be stored in the patient device as a patient record. Such record would be used to constitute a hydrocephalus database. This database can play a vital role in treatment of hydrocephalus. In addition, it could be useful in shunt diagnosis process.

The mechatronic shunt system is now under development and one of the benefits of using such system is the ability of non invasively monitoring the hydrocephalus patients in real time. Based on the proposed design of such shunting system, a daily ICP report would be generated and wirelessly send to the patient device. This report would include important useful information that would used to derive ICP and flow parameters such as mean ICP, mean valve flow, mean absolute deviation.

The first contribution of developing such method is enabling the system to early detect and warn of any expected shunt fault before it is occurred based on the parameters trends and patterns. The trends of the parameters are utilised to monitor the behaviour of ICP signals and then to conclude the current status of the shunt components. In addition, it used to predict the possibility of any future fault in shunt components.

Trend detection algorithm is proposed and applied in this study to detect the trends of the derived parameters of simulation output. In addition, simple predictive procedures are developed to estimate the required period of time needed for (ICP) to be in abnormal range.

The strong relation between trends of the parameters and the degree of valve blockage is used to predict any future fault in the valve and calculate the expected time that is required to make a valve in full blockage status. The proposed method is also used to deal with various shunt complications such as valve leakage problem. The novelty of using a mechatronics shunting system is the ability of autonomously modifying valve schedule when it is needed to deal with patients requirements. The second contribution of developing such method is to autonomously reflecting the effect of faults detection on valve schedule. An auto valve schedule approach is illustrated and simulated in this section. Such approach would deal with ICP rising by calculating and modifying the new valve schedule parameters. The new schedule parameters values (open duration, frequency of opening) are calculated based on the degree of changing in ICP due to shunt faults, increase/deacrease CSF production or increase/deacrease the natural drainage or blockage degree. Such approach would delay the risks accompanied with fault as long as possible. A block diagram shows in Figure 8.1 illustrates the procedures of the proposed self learning method.

## 8.2 Methodology

### 8.2.1 Hydrocephalus Database

The researcher has proposed in Chapter 3 a design of shunt daily report that would be sent from implantable system into external patient device. Such report would be saved in a local database which will be hosted in patient device. A valve schedule design has been proposed in previous chapters as shown in Figure 8.2 where *(d)* is the open duration and *(p)* is the period between two consecutive opening times. Base on this schedule, a sample of ICP readings would be collected very short time before the opening and closing of the valve to measure the effect of open duration on ICP.

Various parameters which have strong correlations with expected shunt complications have been selected and calculated for each collected ICP sample. These parameters are mean ICP, mean absolute deviation (MAD) and valve flow. They were calculated for 6-second time windows.

The calculated ICP and flow parameters, samples of ICP readings, time of collect such samples and the times of calculate such parameters will make up the daily report that eventually accumulate in the patient device database.

A self learning method would use this database for learning and achieve the goals of early faults detection and auto valve schedule updating. To achieve this, the

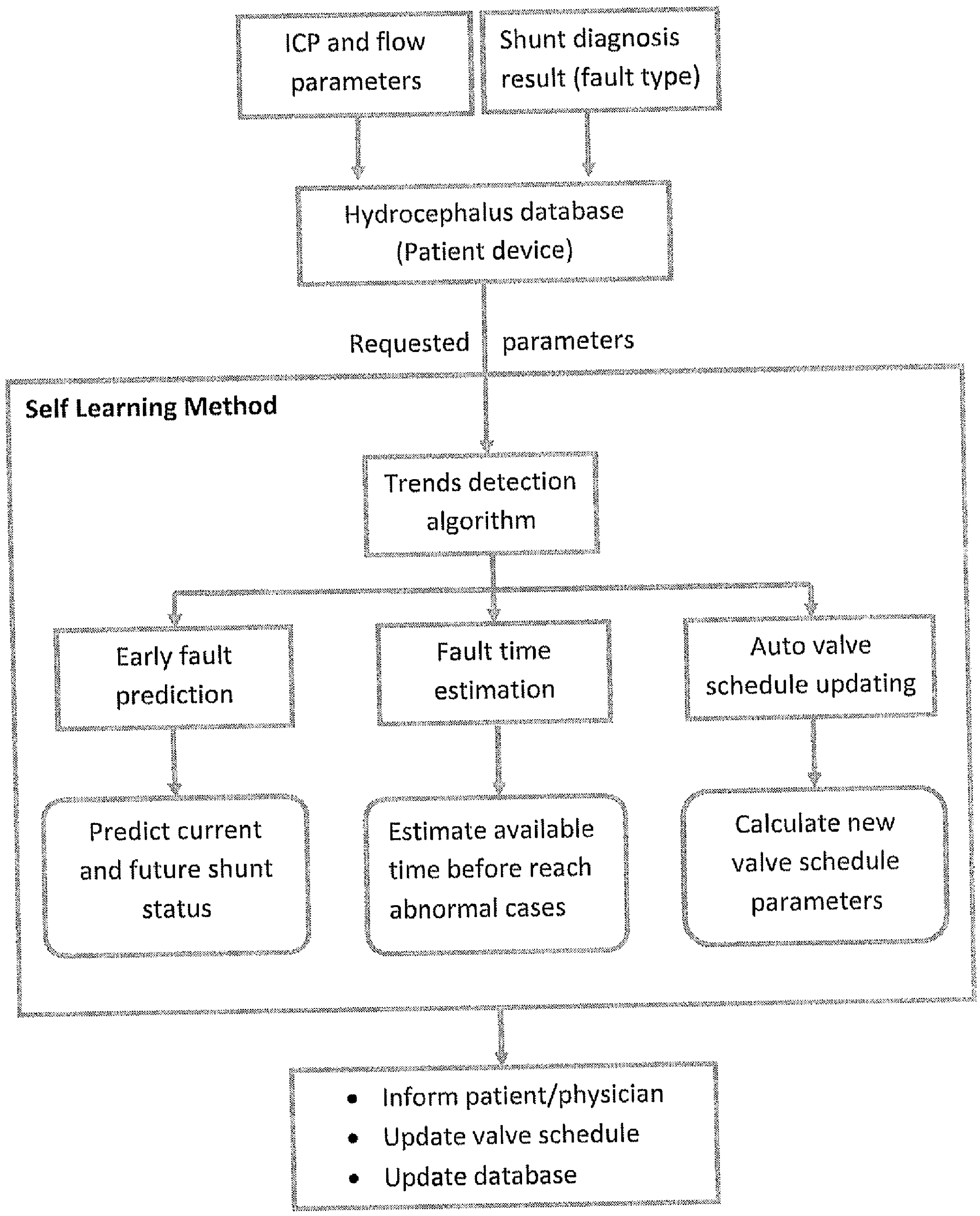



FIGURE 8.1: A block diagram of the proposed self learning method .

database is searched for valuable information ( ICP and flow parameters, fault type, time and date) to be used for detecting any patterns and trends in ICP with time. A sample of such information is shown in Figure 8.3.

This information includes the following parameters: the time of collecting ICP

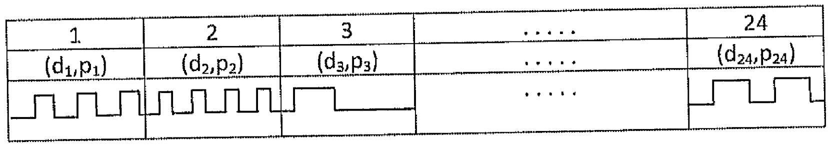



FIGURE 8.2: An hourly schedule for the implanted valve and ICP sensor.

| Slot-Number | Sample Time (hh:mm) | Mean $ICP_{open}$ (mmHg) | Mean $ICP_{close}$ (mmHg) | Mean Flow (ml/min) | MAD $_{open}$ (mmHg) | MAD $_{close}$ (mmHg) | Diagnosis result |
|---|---|---|---|---|---|---|---|
| 1 | 00:10 | 7 | 3 | 0.03 | 0.5 | 0.1 | No fault |
| 2 | 00:20 | 7 | 3 | 0.03 | 0.5 | 0.1 | No fault |
| 3 | 00:30 | 7 | 3 | 0.03 | 0.5 | 0.1 | No fault |
| 4 | 00:40 | 8.5 | 4 | 0.01 | 0.8 | 0.3 | No fault |
| 5 | 00:50 | 8.6 | 4 | 0.01 | 0.8 | 0.3 | No fault |
| ----- | ----- | ----- | ----- | ----- | ----- | ----- | ----- |
| 47 | 23:50 | 12 | 6.2 | 0.005 | 1.5 | 0.9 | No fault |
| 48 | 24:00 | 14 | 7.3 | 0.005 | 2.1 | 1.1 | No fault |

FIGURE 8.3: A sample of generated self learning report.

samples, the calculated mean ICP, MAD, valve flow, slot number, the result of diagnosis system for this slot based on the diagnosis system (explained in Chapter 6).

### 8.2.2 Trends Detection

In this work, the previous parameters were derived for a period of seven days. The trend and pattern of mean ICP were detected during this period. Three trends possibilities (positive, negative and no trend) have been covered in this study. A daily average of mean ICP values is calculated at the beginning of open duration. An algorithm is proposed for trend detection of selected parameter (mean ICP) in specific time. This algorithm is illustrated in Figure 8.4.

A comparison between the parameter values is carried out. Based on this comparison, a pattern and characteristic of this parameter has been detected. The relation and the trends of increasing or decreasing the values of the parameter are the outcome of the learning method. Based on the type of trend, a decision can

**Trend Detection Algorithm for ICP parameters**

1. Request ICP report from local hydrocephalus database
2. For each daily report :
    - Calculate the daily average of each ICP parameters ( mean ICP_open, mean ICP_close, MAD_open, MAD_close, mean valve flow)
3. Repeat step two for every day
4. In day three:
    - Compare the values of each parameter with its previous values (day two and day one)
    - If the comparison result is the values are continuous increased,

    Then positive trend
    Else

    - If the comparison result is the values are continuous decreased,

    Then negative trend

    Else
    Irregular trend
5. Repeat step four for every three days.
6. End

FIGURE 8.4: The proposed trend detection algorithm.

be made whether there is a possibility of shunt fault or valve schedule could be poor. The possibility of poor schedule is very low and such case can be detected by using other methods such as expert system. In case of the positive trend, it can be concluded that there is valve blockage possibility. Albeit ICP is still within normal range, but there is systematic rise in ICP that would cross the normal range within certain period of time. Thus, enabling the system to detect the fault in its early stages. Knowing that the fault at this stage cannot be detected by the diagnosis system since its effect on the intracranial hydrodynamics is still minimal and the diagnosis system deals with the faults after they occurred.

On the other hand, in case of the detected trend being negative, this would clarify that the current valve schedule is not suitable for the current status of the patient or due to valve leakage. In both cases, there is a need to modify the valve schedule to delay the danger of propagated such problem..

The proposed method also has the ability to manage any irregular change in the trend. In this case,this can be explained by instability of the production of CSF and the patient need more care.

### 8.2.3 Fault Time Estimation

The detection of parameter trend and its direction was used to predict the fault possibility. Based on this trend, a daily rate of increases/deacreases in the parameter value due to rise in ICP or valve blockage is calculated by taking the derivative of the trend with time.

In addition, the estimated time ($t_{AB}$) for the effect of the fault to be observed through the abnormal intracranial hydrodynamics can be calculated as follows,

$$t_{AB} = \frac{\overline{ICP}_{UL} - \overline{ICP}_{current}}{\text{Rate of } \overline{ICP} \text{ change}} \tag{8.1}$$

where $\overline{ICP}_{UL}$ is the upper normal limit,$\overline{ICP}_{current}$ is mean average of mean ICP for current day.

$t_{AB}$ gives an indication of the time available before the ICP crosses the upper limit, thus if valve is revised within this time, patient's discomfort and subjection to danger can be avoided.

Furthermore, a full valve blockage limit can be estimated based on numerical simulation and time ($t_{FL}$) for the valve to reach a full blockage limit can be calculated as follows,

$$t_{FL} = \frac{\overline{ICP}_{FL} - \overline{ICP}_{current}}{\text{Rate of } \overline{ICP} \text{change}} \tag{8.2}$$

where $\overline{ICP}_{FL}$ is the estimated mean ICP at full blockage.

On the other hand, in case of negative trend, a drop in the value of mean ICP due to various reasons, *e.g.* valve leakage can be calculated by taking the derivative of the trend model with time.

Then, the estimated time ($t_{AL}$) for the effect of the detected fault to be observed through the abnormal intracranial hydrodynamics can be calculated as follows,

$$t_{AL} = \frac{\overline{ICP}_{current} - \overline{ICP}_{LL}}{\text{Rate of } \overline{ICP} \text{ change}} \tag{8.3}$$

where $\overline{ICP}_{LL}$ is the mean ICP lower normal limit.

$t_{AL}$ gives an indication of the time available before the ICP crosses the lower limit, thus if valve is revised within this time, patient's discomfort and subjection to danger can be avoided.

As a result, fault predicted time can give an indication for the physician about the available time for shunt revision before endangering patient's life.

Figure 8.5 shows the early fault detection ICP parameters, *i.e.* lower normal limit, upper normal limit and full valve blockage limit. ICP is measured in millimeters of mercury (mmHg) and, at rest, is normally between 7 mmHg and 15 mmHg for a supine adult [106]. Based on this, it is assumed that the lower normal value of ICP is 5 mmHg and the upper normal limit is 17 mmHg.

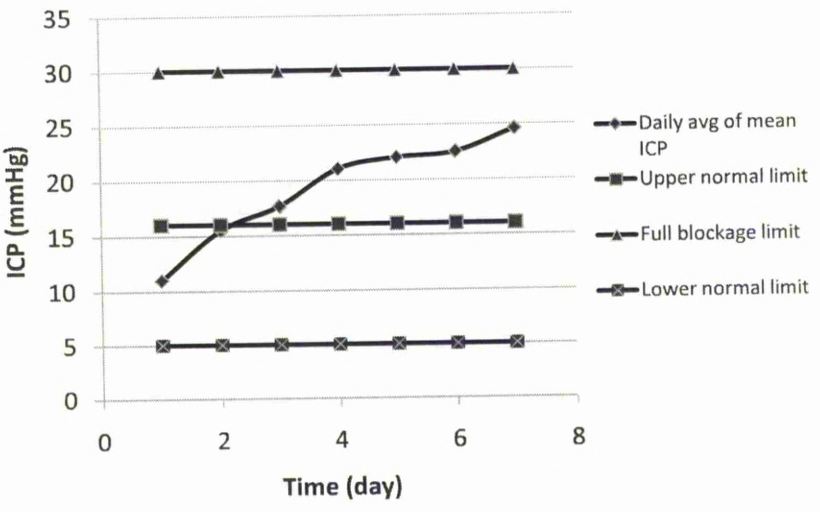



FIGURE 8.5: Early fault detection parameters.

The outline of the proposed algorithm for early fault detection is illustrated in Figure 8.6. The fault detection remedy is discussed in next section.

### 8.2.4 Auto Valve Schedule Updating

The faults prediction and detection methods have been illustrated In previous sections of this chapter as well as trend detection and fault time estimation. The outcome of such methods would be used to inform the system with such predicted faults and estimate the time before occurrence such fault Thus, there is a real need for instantaneous solution that autonomously modify the valve schedule to deal with such problem. A method is proposed that calculates the optimum valve schedule parameters, *i.e.* opening and closing durations of the valve. In this method, the system can calculate the new valve schedule and update it based on the effect of the fault on the intracranial hydrodynamics.

**Early Fault Detection Algorithm**

1. Check the detected trends
2. If positive trends :
    - Calculate the recent increase rate in ICP
      Based on simulation result:
      $$rate\ of\ \overline{ICP}\ change = 6.857/_t$$
    - Calculate the estimated time needed for ICP to be abnormal
      $$t_{AB} = \frac{\overline{ICP}_{AUL} - \overline{ICP}_{current}}{rate\ of\ \overline{ICP}\ change}$$
    - Calculate the estimated time for the shunt to be in full blockage
      $$t_{FB} = \frac{\overline{ICP}_{FL} - \overline{ICP}_{current}}{rate\ of\ \overline{ICP}\ change}$$
    - Call valve schedule updating to solve the predicted problem (if schedule already updated ignore this step)
    - Warns for a need for shunt revision
3. Else if negative trends :
    - Calculate the recent decrease rate in ICP
      Based on simulation result:
      $$rate\ of\ \overline{ICP}\ change = \boxed{0.3012 * t^3 - 3.332 * t^2} + 9.8342 * t - 8.9361$$
    - Calculate the estimated time for ICP to be abnormal
      $$t_{AL} = \frac{\overline{ICP}_{current} - \overline{ICP}_{LL}}{rate\ of\ \overline{ICP}\ change}$$
    - Call valve schedule updating to solve the predicted problem (if schedule already updated ignore this step)
    - Warns for a need for shunt revision
4. Else if irregular trends:
    - Warns for a need of more attention to the patient
5. Else : The expected status of the shunt is normal and the valve schedule update is working
6. end

FIGURE 8.6: Sequence of early fault detection algorithm.

The valve schedule updating method is investigated to deal with effect of both valve blockage and leakage faults. In valve blockage which is presented by positive trend, two cases were covered. The first case is when the detected trend is positive and the ICP is still within normal range. In this case, the time needed (dt) to reduce the rise in ICP to reach lower limit can be calculated as shown in Figure 8.7.

The new schedule would be used to regulate the valve based on the detected trend. The second case is when the detected trend is positive and the ICP is abnormal (above the upper limit). In this case, the proposed method involves the following steps as illustrated in Figure 8.7. First, the time ($dt_{min}$) needed to reduce the rise in ICP (due to blockage or fault) to the upper normal limit is calculated. Second, the time ($dt_{max}$) needed to reduce the rise in ICP to the lower normal limit is also calculated. Then, the average of the calculated times ($dt_{average}$) is calculated, *i.e.* time needed for ICP to be within the normal range. These values will be used as a new schedule parameters for the valve in order to overcome (eliminate) the effect of the gradual increase in the degree of the blockage as follow: If the rise in ICP is high (more than 20mmHg), ($dt_{max}$) will be used as a new open duration for the valve. If the rise in ICP is low (less than 20mmHg), ($dt_{average}$) will be used as a new open duration for the valve.

In valve leakage which is presented by negative trend, two cases also were covered. The first case is when the detected trend is negative and the ICP is still within normal range. In this case, the time needed (dt) to retrieve the drift in ICP to reach upper normal limit is calculated as shown in Figure 8.8. This value will be used as a new schedule parameter to regulate the valve based on the detected trend. The second case is when the detected trend is negative and the ICP is abnormal (below the lower limit). In this case, the proposed method involves the following steps as illustrated in Figure 8.8. First, the time needed ($dt_{min}$) to retrieve the drift ICP to reach lower limit is calculated. Second, the time needed ($dt_{max}$) to retrieve the drift ICP to reach upper limit is calculated. Then, the average time ($dt_{avg}$) to retrieve the drift ICP to be within normal range also is calculated. These values will be used in selecting a new schedule parameters in order to overcome (eliminate) the effect of the gradual decreases in ICP due to

**Valve Schedule Updating Algorithm (positive trend)**

1. Positive trend with abnormal ICP case:
   - Calculate the needed time ($dt_{min}$) to reduce the rise in ICP to reach upper limit

$$dt_{min} = \frac{Daily\ \overline{ICP}\ _{open} - Upper\ normal\ limit}{Rate\ of\ \overline{ICP}\ change}$$

   - Calculate the needed time ($dt_{max}$) to reduce the rise in ICP to reach lower limit

$$dt_{max} = \frac{Daily\ \overline{ICP}\ _{open} - Lower\ normal\ limit}{Rate\ of\ \overline{ICP}\ change}$$

   - Calculate the average time ($dt_{avg}$) to reduce the rise in ICP to be within normal range

$$dt_{avg} = \frac{dt_{max} + dt_{min}}{2}$$

   - Based on the percentage of rising ICP comparing with the normal range, update valve schedule

   1) If the rise in ICP is high:

      New $d_o = dt_{max}$, $d_o$ is valve open duration

   2) else If the rise in ICP is low:

      New $d_o = dt_{avg}$

   - Follow the new valve schedule
   - End

2. Positive trend with normal ICP case:
   - Calculate the needed time (dt) to reduce the rise in ICP to reach lower limit

$$dt = \frac{Daily\ \overline{ICP}\ _{open} - Lower\ normal\ limit}{Rate\ of\ \overline{ICP}\ change}$$

   New $d_o < dt$, $d_o$ is valve open duration

   - Follow the new valve schedule
   - End

FIGURE 8.7: The sequence of auto valve schedule updating algorithm (positive trend).

leakage as follows: if the drift in ICP is high (less than -5mmHg), ($dt_{max}$) will be used as a new schedule parameter for the valve. If the drift in ICP is low (grater than -5mmHg), ($dt_{average}$) will be used as a new schedule parameter for the valve.

**Valve Schedule Updating Algorithm (Negative trend)**

1. Negative trends with abnormal ICP case :
   - Calculate the needed time ($dt_{min}$) to retrieve the drift ICP to reach lower limit

$$dt_{min} = \frac{Daily\ \overline{ICP}_{\ open} - Lower\ normal\ limit}{Rate\ of\ \overline{ICP}\ change}$$

   - Calculate the needed time ($dt_{max}$) to retrieve the drift ICP to reach upper limit

$$dt_{max} = \frac{Daily\ \overline{ICP}_{\ open} - Upper\ normal\ limit}{Rate\ of\ \overline{ICP}\ change}$$

   - Calculate the average time ($dt_{avg}$) to reduce the rise in ICP to be within normal range

$$dt_{avg} = \frac{dt_{max} + dt_{min}}{2}$$

   - Based on the percentage of ICP drift comparing with the normal range, Update valve schedule
     1) If the drift in ICP is high:

$$\text{New } d_o = \text{Current } d_o - dt_{max}$$

     2) else If the drift in ICP is low:

$$\text{New } d_o = \text{Current } d_o - dt_{avg}$$

   - Follow the new valve schedule

2. Negative trend with normal ICP case:
   - Calculate the needed time (dt) to retrieve the drift ICP to reach upper normal limit

$$dt = \frac{Daily\ \overline{ICP}_{\ open} - Upper\ normal\ limit}{Rate\ of\ \overline{ICP}\ change}$$

New $d_o$ = $dt$, $d_o$ is valve open duration

   - Follow the new valve schedule
   - End

FIGURE 8.8: The sequence of auto valve schedule updating algorithm (negative trend).

In addition, a model of the relation between mean ICP and optimum open and closed durations that resulted from an algorithm developed by Momani *et al.* [75] was implemented in modifying the valve schedule. This algorithm was proposed to help in developing a valve schedule based on the patient's own intracranial pressure data and a novel figure of merit, thus providing the physician with an easy tool that facilitates the use of the mechatronic valve. The algorithm was implemented in $matlab^{TM}$ and $simulink^{TM}$. As a result of this algorithm, the relation between ICP and optimum open duration $d_{ON}$ and closed duration $d_{OFF}$ (that has maximum FoM) was investigated. Numerical simulations were performed for each hour at different average ICP values and the FoM was calculated for each trial. As a result, $d_{ON}$ and $d_{OFF}$ corresponding to the maximum FoM was projected against the average ICP values. The following models were used to calculate the new values of $d_{ON}$ and $d_{OFF}$ based on daily average of mean ICP in case of normal shunt,

$$d_{ON} = 0.0082 \times \overline{ICP}^3 - 0.5705 \times \overline{ICP}^2 + 13.039 \times \overline{ICP} - 91.2460 \qquad (8.4)$$

$$d_{OFF} = 0.0346 \times \overline{ICP}^3 - 2.3399 \times \overline{ICP}^2 + 51.7150 \times \overline{ICP} - 356.1000 \qquad (8.5)$$

where $\overline{ICP}$ is the average of mean ICP for current day.

The results of the two methodology (the proposed methodology and Momani methodology) were compared. Figures 8.7 and 8.8illustrates the outline of auto valve schedule updating algorithm.

The proposed method was evaluated using numerical simulations. Figure 8.19

shows the evaluation results, where the selected parameters were calculated before and after applying this method, *i.e.* daily mean ICP, daily average of mean ICP when the valve is closed and open. A performance measure was derived to evaluate the proposed method by calculating the total deviation of daily mean ICP from upper normal limit. This performance measure was calculated before and after applying the proposed technique for specific time interval. The performance factor (PF) is calculated as follows,

If $(ICP_{mean}(d) - AUL) > 0$ then :

$$P_{AB1} = \sum_{d=1}^{n} (ICP_{mean}(d) - AUL) \tag{8.6}$$

Else

$$P_{AB2} = \sum_{d=1}^{n} (AUL - ICP_{mean}(d)) \tag{8.7}$$

$$P_{AB} = P_{AB} + P_{AB2} \tag{8.8}$$

$$PF = 1 - \frac{P_{AB(after)}}{P_{AB(before)}} \tag{8.9}$$

where, $P_{AB}$ is the summation of the difference between daily mean ICP and upper normal limit, AUL is the upper abnormal limit, $\text{ICP}_{mean}$ is the average of mean ICP per day and n is the number of days. The closer to unity PF is, the better the performance of schedule modifying. PF values vary between 0 and 1.

### 8.2.5 Fault Modeling

Numerical simulations have been performed using Simulink model that reproduces intracranial hydrodynamics of hydrocephalus patients using historical ICP data [71]. This model was used as a dynamic environment to reflect the effect of adding a mechatronic valve on the intracranial hydrodynamics. A time-based valve schedule was used to control the opening and closing of this valve.

The most common shunt faults are valve blockage and leakage [7]. Thus, these faults were investigated in this study. The effect of such faults on the intracranial hydrodynamics were modelled using Simulink where they were incorporated into the intracranial hydrodynamics model. This has been modified to simulate different degrees of valve blockage and leakage. The shunting system has been monitored for seven days where the ICP readings have been collected and the ICP parameter values have been calculated. The simulation has started with normal shunt without any fault and then the faults were introduced.

Blockage degree parameter was represented by $R_t$. $R_t$ is a resistance that is made up of valve resistance and resistant due to blockage. The increase in $R_t$ due to blockage is assumed to have exponential relation with time that reflect the behaviour of blockage formation as follows,

$$R_t = \mathrm{A} \times e^{-Bt} \tag{8.10}$$

Two points were used to estimate the constant A and B of the model: (1) at zero time, it was assumed no fault, thus $R_t$= valve resistance (2) at the end of seven days it was assumed that $R_t$ reaches seven times the valve resistance. As the result of substitution $R_t$ can be model as follows,

$$R_t = 263.763 \times e^{1.93\times10^{-5}\times t} \tag{8.11}$$

After setting the value of $R_t$, the effect of the valve blockage on the performance of the shunt during seven days was noticed through the rise in ICP readings as well as reducing valve flow.

The trends of changing of ICP and valve flow parameters with time due to faults have been utilised in early detecting of such faults and in estimating the available time before reaching ICP abnormality and full blockage.

The method for modifying the valve schedule has been applied and the new opening valve durations have been autonomously calculated for each blockage degree. These new open durations have been applied in real time and the effect of such new schedule has been illustrated in Figure 8.9.It can be noticed that, mean ICP stay longer time within acceptance limit (less than 20mmHg) comparing with mean ICP before apply this method as shown in Figure 8.19.

The proposed schedule modifying method has been evaluated using simulation environment by comparing the effect of valve blockage for the selected parameters before and after applying such method. The experimental work includes four procedures: (1) generate a summary of important parameters to help in the learning process from database, (2) using proposed methods for early fault detection and abnormality time estimation to learn from the parameters that are derived from database, (3) applying autonomous valve schedule updating method to find a temporary solution to deal with the faults,and (4) finally use numerical simulation to measure the performance of these methods.

By comparing between mean ICP before and after applying the proposed method, it is found that the value of mean ICP was reduced due to applying the valve

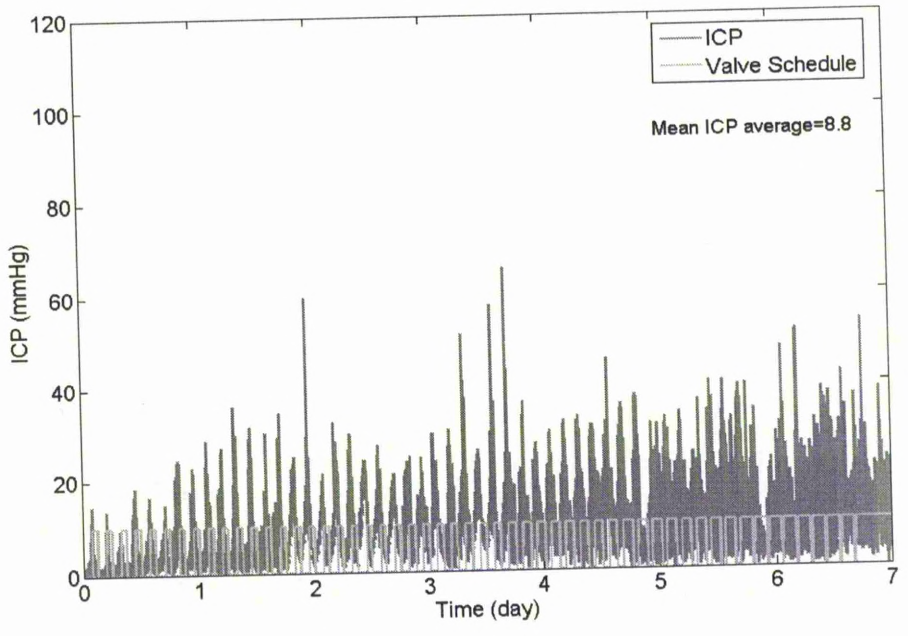



FIGURE 8.9: The effect of autonomous valve schedule updating method for selected days.

schedule updating method and it is maintained for longer time within normal range than before.

## 8.3 Results and Discussion

In this work, a self learning method of hydrocephalus shunting system was investigated and simulated. Two types of faults, *i.e.* valve blockage and leakage, were simulated using $Simulink^{TM}$ and $Matlab^{TM}$. Figure 8.10 and 8.11 illustrate ICP traces after incorporating the blockage and leakage faults, respectively. In addition, unstable increases/decrease of ICP was simulated as shown in Figure 8.12 Trends of various ICP parameters which are derived from the simulated ICP data have been used to detect the fault in its early stages and to monitor the effect of such fault on shunt performance step by step. Three types of trends were investigated; positive, negative, and no trends. Figure 8.13 illustrates the predicted

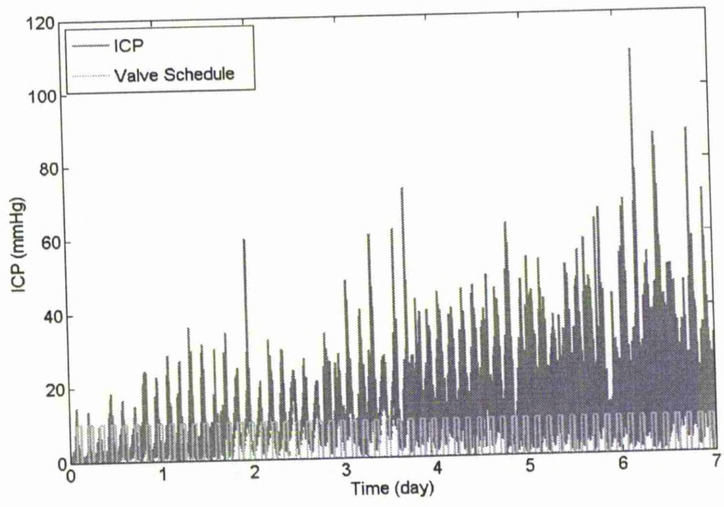



FIGURE 8.10: The effect of valve blockage on ICP trace.

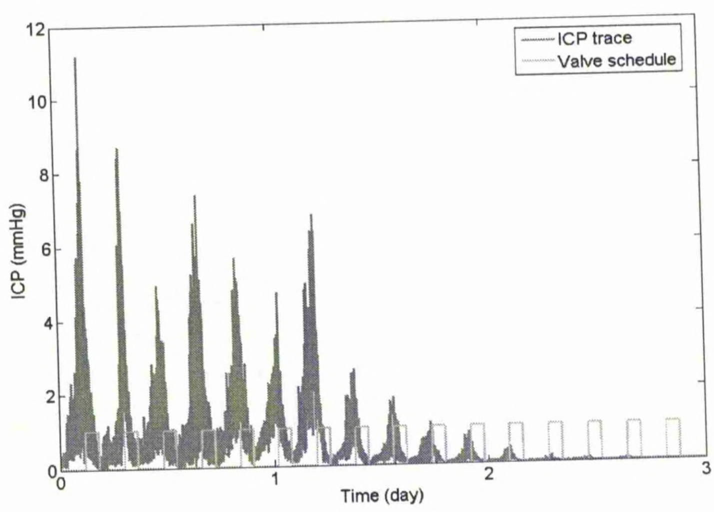



FIGURE 8.11: The effect of valve leakage on ICP trace.

effect of valve blockage on the trends of daily average of mean ICP for seven days.

This figure shows that there is a positive trend which means the ICP is rising albeit the valve schedule is used to regulate the valve. This increase is caused by increasing in the degree of valve blockage. Logarithmic trendline is selected for mean ICP where it is a best-fit curved line that is most useful when the rate of

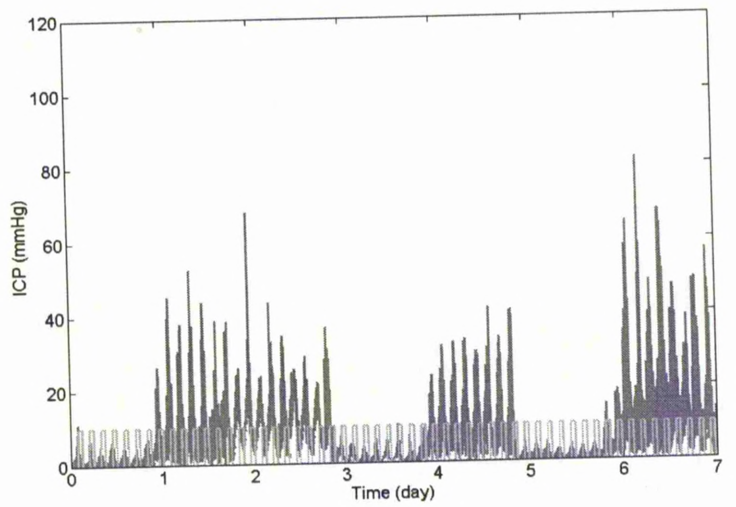



FIGURE 8.12: Unstable changing of ICP trace.

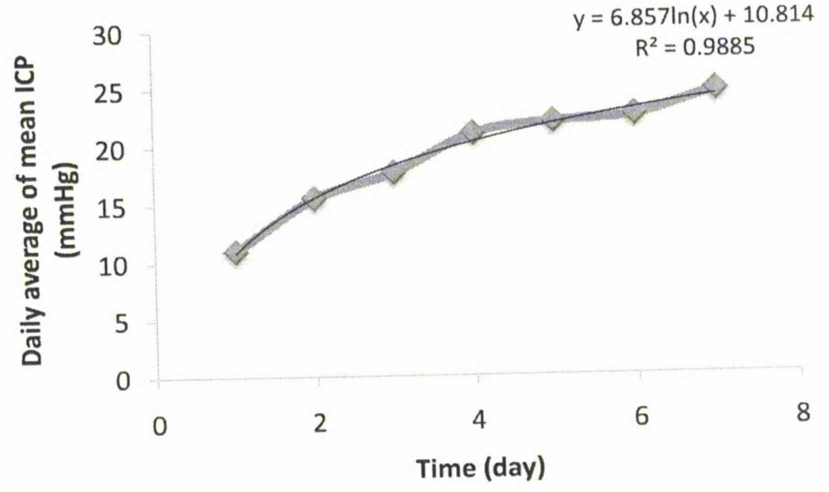



FIGURE 8.13: The trend of daily mean ICP due to blockage occurrence.

change in the data increases or decreases quickly and then levels out. Note that the trend can be approximated to be logarithmic with R-squared value equals 0.98 as follows, which is a relatively good fit of the line to the data.

$$\overline{ICP} = 6.857 \times \ln(t) + 10.841 \tag{8.12}$$

In case of positive trend, the daily rate of increase in mean ICP is calculated by deriving the model of the positive trend with respect to time and this gives the following equation,

$$\text{Rate of } \overline{ICP} \text{ change} = 6.857/t \tag{8.13}$$

where $t$ is the corresponding time (in days).

Figure 8.14 illustrates an example of negative trend. It shows the effect of valve leakage on the trends of daily average of mean ICP for seven days. It can be noticed that the daily mean ICP is continuously reduced due to valve fault.

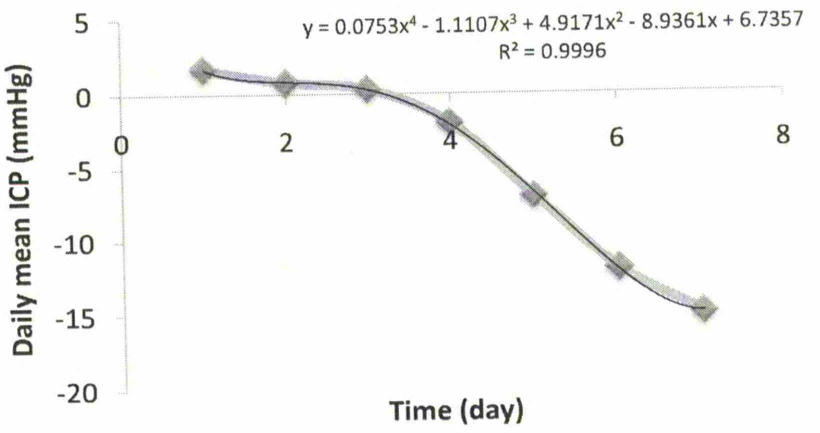



FIGURE 8.14: The change in trend of daily mean ICP due to leakage within time.

This trend is approximated to be polynomial trendline as illustrated below. Such trendline is a curved line that is most useful when data values rise or fall at increasingly higher rates. From previous, the value of mean ICP can be calculated based on time as follows,

$$\overline{ICP} = 0.0753 \times t^4 - 1.107 \times t^3 + 4.917 \times t^2 - 8.9361 \times t + 6.7357 \tag{8.14}$$

The rate of drop in mean ICP due to valve leakage is calculated by taking the derivative of the negative trend as follows,

$$\text{Rate of } \overline{ICP} \text{ change} = 0.3012 \times t^3 - 3.332 \times t^2 + 9.8342 \times t - 8.9361 \qquad (8.15)$$

Figure 8.15 illustrates an example of no trend. It can be seen that ICP changes in a series of irregular rise and drop cycles due to many reasons such as poor valve schedule.

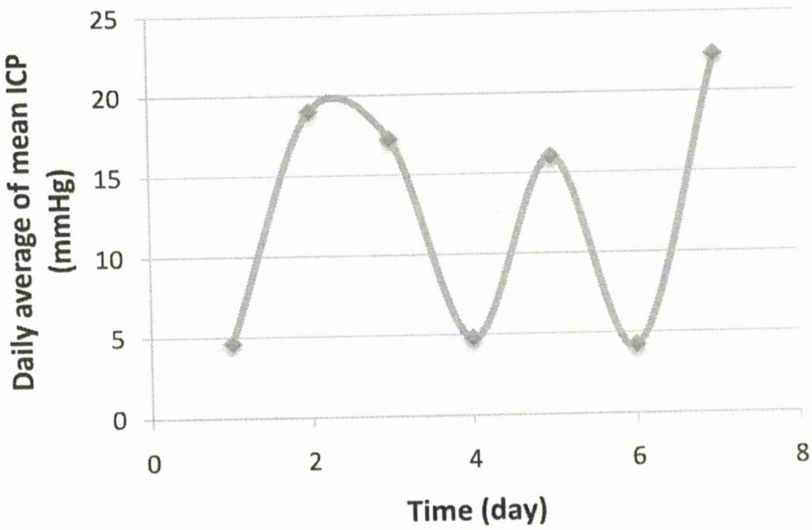



FIGURE 8.15: The irregular change in trend of daily mean ICP within time.

In addition, the estimated times for ICP to reach the upper normal, lower normal and the full blockage limits are calculated. Figure 8.16 summaries these values for each corresponding day before and after apply the valve schedule updating algorithm.

An automatic valve schedule updating method is used to temporarily deal with any early fault detection until the patient checked up by his/her physician. By using such method, the schedule will be manipulated in away to maintain ICP within normal range for longer compared with the time before applying such method. For example in *Momani's* algorithm [71], Equations 8.4 and 8.5 were used to calculate the new schedule parameters. Figure 8.17 summaries these values for each corresponding day. In addition, valve schedule parameters were calculated based on the proposed auto valve schedule updating method and Figure 8.18 summaries these values for each corresponding day. Furthermore, hydrocephalus treatment information as well as shunt diagnosis information can be used to build a useful hydrocephalus database for better understanding of hydrocephalus and shunt malfunctions. That can lead to improve shunt performance and at the same time optimise the treatment.

Two schedule updating methods, the proposed auto valve schedule and Momani's method, were used to deal with the predicted faults. Figure 8.19 demonstrates the effect of applying both these methods. It can be noticed that mean ICP was reduced compared with that before applying the method. This will delay the risky effect of propagating such fault. It can be noticed from Figure 8.16 that the two methods succeeded in delaying the times needed to reach both abnormal and full blockage.

In addition, the performance factor (PF) was used to evaluate the efficiency of the previous methods. By applying the equation 8.9, PF value was for the first method (0.94) whereas, the second method scored (0.7).

Based on these results and Figure 8.19, it can be observed that the proposed method achieved better result than Momani method. This is due to that Momani method was designed to model optimum schedule parameters for shunt with no faults, whereas the proposed one is targeting shunts with faults.

## 8.4 Conclusion

To conclude, implementing the proposed methodology can result in detection of valve faults at early stages, estimation of the time required for the ICP to be abnormal and estimate the time required for the valve to reach full blockage case. Furthermore, the method proposed to autonomously manage the valve schedule can temporarily reduce/delay the effect of the detected fault. By applying this method, the risks of such faults on patient's life can be reduced. In addition, the patient's suffering due to valve revisions would be reduced by applying such method.

With these features, the proposed learning method would enable the proposed shunting system to learn from the available ICP data in case of hydrocephalus treatment and shunt diagnosis. By using such method, valuable information about hydrocephalus and shunt diagnosis would be available for future learning to improve treatment and management of hydrocephalus as well as for the specific researchers in this area. The outcome of this work are investigate a self learning method for shunt diagnosis, propose a trends detection algorithm for ICP parameters, proposed a prediction method for early fault detection and proposed auto valve schedule updating method.

| Day | Daily mean ICP(mmHg) | Rate of daily change in mean ICP(mmHg/day) | Time (day) to reach AUL ($t_{AB}$) | Time (day) to reach FUL ($t_{FL}$) |
|---|---|---|---|---|
| 1 | 11 | 6.857 | 0.72 | 2.77 |
| 2 | 15.4 | 3.4285 | 0.14 | 4.23 |
| 3 | 17.64 | 2.285666667 | -0.71 | 5.40 |
| 4 | 21 | 1.71425 | -2.91 | 5.25 |
| 5 | 21.99 | 1.3714 | -4.36 | 5.84 |
| 6 | 22.48 | 1.142833333 | -5.67 | 6.57 |
| 7 | 24.54 | 0.979571429 | -8.72 | 5.56 |

*(-) indicates that the value of daily mean ICP has passed the AUL or FUL limit.

(a)

| Day | Daily mean ICP(mmHg) | Rate of daily change in mean ICP(mmHg/day) | Time (day) to reach AUL ($t_{AB}$) | Time (day) to reach FUL ($t_{FL}$) |
|---|---|---|---|---|
| 1 | 11 | 6.85 | 0.72 | 2.77 |
| 2 | 15.48 | 3.42 | 0.14 | 4.23 |
| 3 | 17.64 | 2.28 | -0.71 | 5.40 |
| 4 | 18 | 1.71 | -1.16 | 7.00 |
| 5 | 17.50 | 1.37 | -1.09 | 9.11 |
| 6 | 16.99 | 1.14 | -0.86 | 11.38 |
| 7 | 16.81 | 0.97 | -0.82 | 13.46 |

*(-) indicates that the value of daily mean ICP has passed the AUL or FUL limit.

(b)

| Day | Daily mean ICP(mmHg) | Rate of daily change in mean ICP(mmHg/day) | Time (day) to reach AUL ($t_{AB}$) | Time (day) to reach FUL ($t_{FL}$) |
|---|---|---|---|---|
| 1 | 6.18 | 6.85 | 1.43 | 3.47 |
| 2 | 14.81 | 3.42 | 0.34 | 4.43 |
| 3 | 15.86 | 2.28 | 0.06 | 6.18 |
| 4 | 19.48 | 1.71 | -2.03 | 6.13 |
| 5 | 19.85 | 1.37 | -2.80 | 7.40 |
| 6 | 20.56 | 1.14 | -3.99 | 8.26 |
| 7 | 22.2 | 0.97 | -6.32 | 7.96 |

*(-) indicates that the value of daily mean ICP has passed the AUL or FUL limit.

(c)

FIGURE 8.16: The estimated times for the ICP to reach the upper normal and the full blockage limits: (a) before apply valve schedule updating algorithm, (b) after apply the proposed algorithm and (c) after apply Momani's algorithm .

| Day | Daily mean ICP before (mmHg) | $D_{off}$(min) | $D_{on}$(min) | Period(min) | Daily mean ICP after (mmHg) |
|---|---|---|---|---|---|
| 1 | 11 | 20 | 10 | 30 | 6.18 |
| 2 | 15.488 | 12 | 4 | 16 | 14.81 |
| 3 | 17.643 | 18 | 6 | 24 | 15.86 |
| 4 | 21 | 18 | 7 | 25 | 19.48 |
| 5 | 21.99 | 18 | 7 | 24 | 19.85 |
| 6 | 22.489 | 17 | 7 | 24 | 20.56 |
| 7 | 24.545 | 15 | 6 | 22 | 22.2 |

FIGURE 8.17: The new valve schedule parameters based on Momani's algorithm.

| Day | Daily mean ICP before (mmHg) | $D_{off}$(min) | $D_{on}$(min) | Period(min) | Daily mean ICP after (mmHg) |
|---|---|---|---|---|---|
| 1 | 11 | 20 | 10 | 30 | 11 |
| 2 | 15.488 | 20 | 10 | 30 | 15.488 |
| 3 | 17.643 | 20 | 10 | 30 | 17.643 |
| 4 | 21 | 17 | 13 | 30 | 18 |
| 5 | 21.99 | 14 | 16 | 30 | 17.5 |
| 6 | 22.489 | 11 | 19 | 30 | 16.99 |
| 7 | 24.545 | 5 | 25 | 30 | 16.81 |

FIGURE 8.18: The new valve schedule parameters based on proposed auto valve schedule updating method.

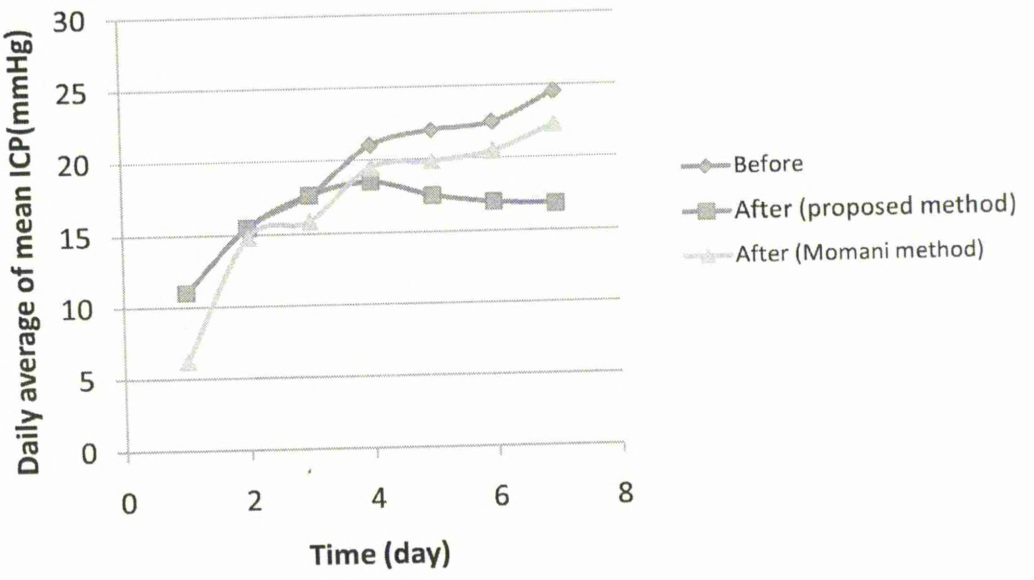



FIGURE 8.19: The change in trend of daily mean ICP due to blockage with time before and after applying auto valve schedule updating methods.

# Chapter 9

# A Multi-Agent Self-Diagnosis System[6]

## 9.1 Introduction

A wireless mechatronic hydrocephalus shunting system was proposed in Chapter 3. The proposed mechatronic shunting system would consist of two subsystems; implantable and external subsystems. The implanted subsystem would wirelessly communicate with a hand-held smartphone operated by the patient, or on the patient' s behalf by a clinician or guardian. In addition, a fuzzy logic system for detecting and identifying mechatronic shunt faults has been proposed in Chapter 6. Such system was used in simulation environment to detect and identify various shunt faults based on ICP and valve flow parameters which would be collected during monitoring the shunt in real time. Also, an expert system for patient feedback analysis was proposed in in chapter 7. The proposed expert system would be used to collect patient feedback by asking specific questions and analyse the patient answers, then a decision would be given based on this feedback whether

[6]Part of this chapter has been published under the title "A Multi-Agent Approach for Self-Diagnosing of Hydrocephalus Shunting System", in 2nd conference of Developments in E-Systems Engineering (DeSE), 6th - 8th Sep 2010, London, UK.

there is a fault or not. Furthermore, a self learning method to learn from hydrocephalus database and ICP information was proposed in Chapter 8. Such method would investigate the trends and patterns of specific ICP and flow parameters to early detect any fault as well as to deal with such fault by a specific action such as modify valve schedule.

In this study, a multi-agent self diagnosis system for hydrocephalus shunt is proposed as an intelligent method to integrate the previous techniques methods. The outcomes of patient feedback system, historical shunt diagnosis database, fuzzy logic system, and intracranial pressure and flowmeter readings will be the core of the proposed multi agent method. These subsystems would integrate and communicate together to deliver both reactive and goal-driven solutions for the diagnosis, at the same time the intelligent part of the system will monitor how well the shunt is performing. reactive make agents perceive their environment, (which may be the physical world, a user via a graphical user interface, a collection of other agents, the internet, or perhaps all of these combined), and respond in a timely fashion to changes that occur in it. With goal-driven feature, agent will act in order to achieve its goals, and will not act in such a way as to prevent its goals being achieved at least insofar as its beliefs permit. There are obvious advantages to reactive approaches such as simplicity, economy, computational tractability, robustness against failure, and elegance. These goals can be achieved by selecting and implementing an agent method in designing this self diagnosis system. Such system would help in early detection of any shunt faults and monitoring the performance of implanted shunt components.

Besides, due to the fact that different types of shunt diagnosis subsystems as well as different types of faults require different types of algorithms. Thus to obtain the best solution, it is reasonable to expect that a significant method of design and build development of such fault detection and isolation of shunting system can be achieved by using a multi agent approach.

An agent is simply another kind of software abstraction, an abstraction in the same way that methods, functions, and objects are software abstractions. An object is a high-level abstraction that describes methods and attributes of a software component. An agent, however, is an extremely high-level software abstraction which provides a convenient and powerful way to describe a complex software entity. Rather than being defined in terms of methods and attributes, an agent is defined in terms of its behaviour. This is important because programming an agent-based system is primarily a matter of specifying agent behaviour instead of identifying classes, methods and attributes. It is much easier and more natural to specify behaviour than to write code.

Agents are now widely discussed by researchers in mainstream computer science, as well as those working in data communication and user interface design. A multi agent system is a system that consists of a number of agents, which is tract with each other, typically by exchanging messages through system or between different systems. In addition, a multi agent system is a dynamic society made up of a number of intelligent agents, so it is an intelligent society. This chapter describes the design of a multi-agent system for self-diagnosis of hydrocephalus shunting system.

## 9.2 Proposed Method

In this study, the design of a multi-agent system for an intelligent self diagnosis system of a hydrocephalus shunting system is proposed. An intelligent concept for intelligent agents is proposed that would deal with any shunt malfunctions in an independent and efficient way, with different agents cooperating and communicating through message exchange, each agent specialised in specific tasks of the diagnosis process. seven types of agents have been proposed to detect any faults in hierarchical way. In addition, One of the most promising methods for the self-diagnosis and monitoring of hydrocephalus shunting system based on a novel multi-agent approach was proposed and discussed.

### 9.2.1 System Components

The intelligent self diagnosis system would consist of both hard and soft components. The overall system is composed of two subsystems (platforms), namely the implanted shunting system and external intelligent system.

#### 9.2.1.1 Hardware Components

The implanted shunting system located inside the body where its hardware components would consist of a microcontroller, a mechatronic valve, a pressure sensor, flowmeter and a wireless transceiver. The hardware of the external intelligent system (called the external patient device) is built up of a smartphone, a wireless transceiver and a microcontroller, along with suitable interfacing circuitry.

#### 9.2.1.2 Software Components

- Agents

  The selected architecture for the multi-agent system in this diagnosis system is the Belief, Desire and Intention (BDI) architecture in which decision making depends upon the manipulation of data structures representing the beliefs, desires, and intentions of the agent. The Prometheus methodology [85] was used to develop the proposed system. As a result of this detailed process, seven agents were developed; five of them located on the external patient device; Decision Maker, Feedback Manager, Database Manager, External Communicator agents, Fault Detection and the other two agents located on the implanted shunting system; Report Manager and Internal Communicator. These agents were selected according to an iterative process where data coupling diagrams and agent acquaintance diagrams were used. The agents within the same platform would communicate through messages. While the agents at different platforms (the external patient device and implanted shunting system) would communicate though the communication agents using an RF data link at 402-405 MHz.

Figure 9.1 presents the agents' interaction diagram for the self diagnosis system. The agents and their roles are as follows. The decision maker agent intelligently analyses the output of the faults detection agent for the following purposes, (i) reach a decision regarding current shunt status, (ii) monitor the performance of the shunt, (iii) assess the quality of the continuous ICP readings. This agent would trigger feedback manager agent to start collecting patient feedback and analyse it. The database manager agent is also initiated for learning from hydrocephalus database in real time. Its responsibility would be to inform the decision maker agent about any expected or predicted faults in the shunt. The fault manager agent initiated to learn from ICP and flow measurements parameters based on fuzzy logic technique to recognise shunt faults. The external and internal communicator agents are responsible for communication between the implanted shunting system and the external intelligent system.

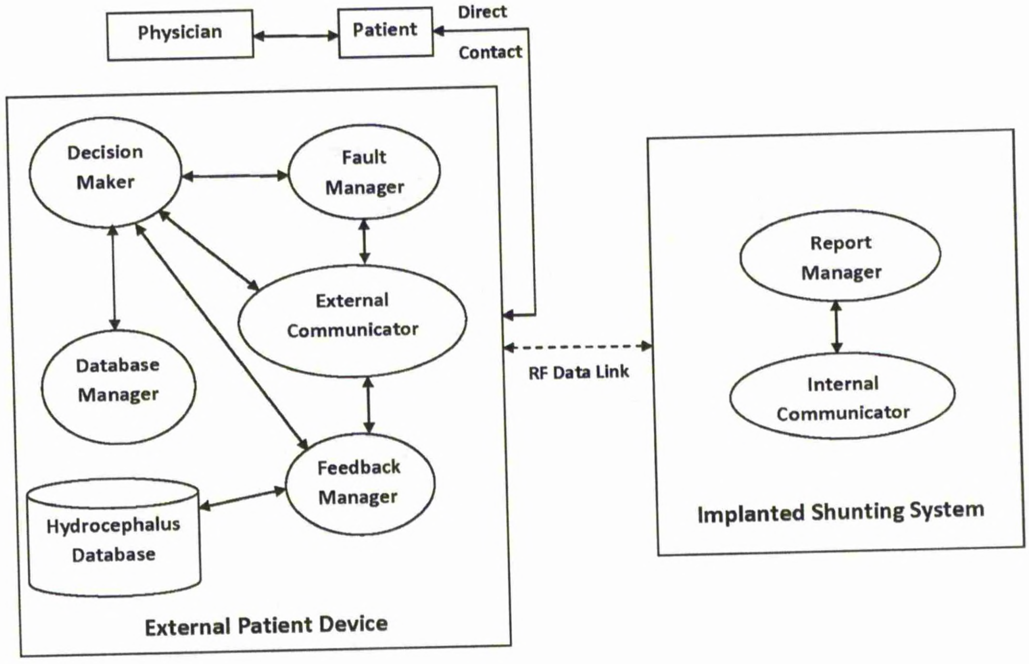



FIGURE 9.1: The layout of the proposed multi-agent system.

### 9.2.2 Sensory Inputs

The sensory inputs of the proposed system are illustrated as follows.

- Patient Feedback Expert System: The patient would participate in his/her treatment by giving direct feedback to show his/her dissatisfaction when he/she is not feeling well at that particular moment, *i.e.* experience symptoms. The feedback system would mainly consist of specific questions and patient answers. The patient would answer the questions by typing his/her feeling when the system start collecting such feedback. The answers would trigger the intelligent system to investigate whether the cause of this dissatisfaction is due to abnormality in ICP, shunt malfunctions or due to other cause.

- Fuzzy Logic System: The real-time ICP readings would be collected by the implanted pressure sensor regularly or upon request. These readings would be sent wirelessly to the external patient device where it will be saved and analysed. A pre-processing mathematical model would derive some ICP and flow parameters such as mean ICP, mean absolute deviation and valve flow subsequently. Then it will be transferred to the fuzzy logic system to classify the values of these parameters. Finally it make a decision based on these values.

- Self Learning Database: The ICP data, flow measurements, derived parameters and other hydrocephalus and shunt information would be stored in local database that would be hosted in patient device. The self learning method can use this database to learn and mine important information about the current shunt status and to predict the future status based on patterns and trends of ICP and flow parameters. The outcome of this method would be expecting a fault and predicting its type or that the shunt is normal.

## 9.3 Analysis, Design and Implementation

The first step of designing a multi agent system is selecting a suitable methodology for the description and design of system software architectures based on the agent approach. Prometheus methodology differs from existing methodologies in that it is a detailed and complete (start to end) methodology for developing intelligent agents which has evolved out of industrial and pedagogical experience. In addition, Prometheus methodology includes description of concepts for designing agents, a process, a number of notations for capturing designs, as well as many "tips" or techniques that give advice on how to carry out the steps of Prometheus' process. As a result of comparing many methodologies [16]-[37], it has been noticed that Prometheus methodology is an appropriate methodology to design and implement a self diagnosis shunting system using multi agent approach. In this method, a detailed process for specifying, designing, implementing and testing agent software system are defined. This method made up of three stages, the first stage is called system specification and its focuses on identifying the basic functionalities of the system, along with inputs (percepts), outputs (actions) and any important shared data sources. The second stage is called architectural design stage and it uses the outputs from the previous stage to resolve which agents the system will include and how they will interact together. The final stage is called detailed design and it looks at the internals of each agent and how it will accomplish its goals within the overall system.

In this work, the Prometheus methodology was used in determining the specifications of the self diagnosis shunting system. In the system specification phase, the goals of the system were identified, case scenarios were developed, the functions of the system were illustrated, and the interface between the system and its environment in term of actions and percepts were specified. Based on the Prometheus methodology, seven agents were developed; Feedback Manager; Fault Manager; Database Manager; Decision Maker; External Communicator; Report Manager and Internal Communicator. These agents would communicate through messages. The architecture design of such system has been illustrated. The agent's rules also are configured based on the system requirements. The details of designing self diagnosis multi-agents system is illustrated below.

### 9.3.1 System Specification

It is not unusual for the initial ideas for a system to be captured very briefly, possibly in a few paragraphs. During system specification, this description must be elaborated and explored, to provide a sound basis for system design and development. In the proposed system, the self diagnosis hydrocephalus shunting system was described as a system with six distinct phases in which the system must operate: implanted diagnosing, patient feedback, fault detection, emergency handling, self diagnosis database analysing and final decision making. During the implanted diagnosis phase, shunt components are instantaneously tested then a diagnosis report is generated which include the initial diagnosing results *i.e.* shunt status, predict fault type, valve schedule slot number and slot status. After testing all valve schedule slots, the implanted shunting system would wirelessly send such diagnosis report to the external system as a part of a daily report. On the other hand, the implanted diagnosis phase has the ability to send an emergency report in case of urgent situations, *i.e.* there are four or more sequential slots have problem.

In fault detection phase, the diagnosis report would be scanned and if there is any need to request samples of ICP readings and flowmeter measurements from the implanted system, such request would be sent to hydrocephalus treatment system to collect such sample with specific length and at specific time, *i.e.* start at the beginning of slot two for two minutes. This sample would be analysed and the ICP parameters (Mean ICP, MAD, Mean flow) would be calculated. A fuzzy logic technique would use these parameters to classify and identify any problem in the shunt components during period of the sample. The final results of fault detection phase would be passed to the final decision phase.

The patient feedback phase would instantaneously request a patient feedback about his/her feeling either at this moment or at previous time. An intelligent decision related to the shunt status is generated from expert system based on patient feedback and then passed to the final decision phase.

In self diagnosis database analysis phase, a searching algorithm would be used to search through the database for similar case to the current case by matching the current symptoms and diagnosis results with all previous cases. Some of the functions performed in this phase are check patterns and trends, perform statical analysis, re-estimate parameters, self updating and more. Such functions would help to early predict and detect any fault, *i.e.* especially in valve blockage case, where the blockage occur gradually not suddenly. The result of searching and matching phase would also be passed to the final decision phase. Finally, agent's rules would be used to make a final decision based on all previous analysis results. The decision would be broadcasted to the patient, the physician, the treatment system and then stored in the diagnosis database.

Typically, using Prometheus, the development of the system specification begins with identifying the external entities (referred to as actors) that will use or interact in some way with the system, and the key scenarios around which interaction will occur. This is done by utilising Prometheus Design Tool (PDT) using the analysis overview diagram as shown in Figure 9.3. Four external entities were identified: patient/parent, physician, implanted system and treatment system entities. These entities have been associated with three main scenarios which correspond to the main external functionality of the system. As well as six internal entities were identified: feedback management, report analysis, fault detection, emergency management, diagnosis database management and decision making entities that will interact with the system. These were associated with five main scenarios which correspond to the main functionality of the system.

After that, the initial diagram is refined by identifying the percepts that are inputs to each scenario, and the actions produced by the system for each scenario, linking them to the appropriate actors as shown in Figure 9.2. For example, the patient or parent submits his/her feedback as a percept (input) to the system and the system performs an action of sending the feedback analysis results to the fault detection functionality. The analysis overview diagram thus defines the interface to the system in terms of the percepts (inputs) and actions (outputs).

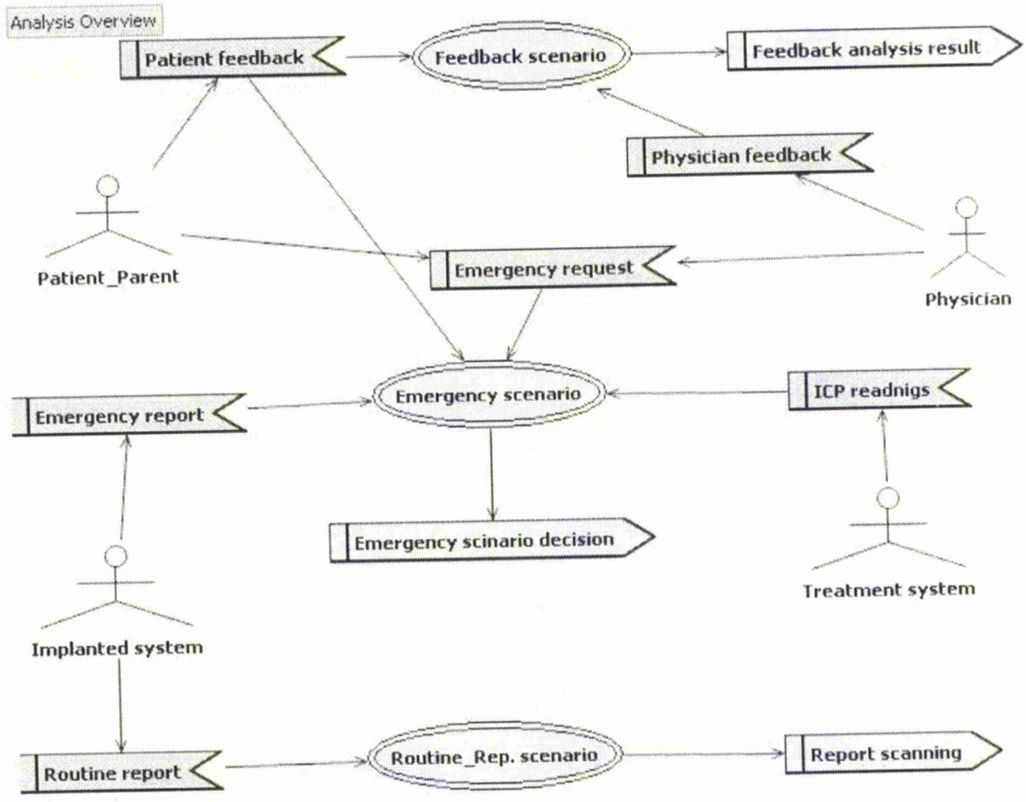



FIGURE 9.2: Refined Analysis Overview Diagram.

The next step is to specify the details of the scenarios that have been identified in analysis overview diagram. A scenario is a sequence of structured steps where each step can be one of: goal, action, percept, or (sub) scenario. Each step also allows the designer to indicate the roles associated with that step, the data accessed, and a description of the step. The initial goal specification, functionalities and scenario development are explained in later section. These preliminary goals, roles and data that are identified are used to automatically propagate information into other aspects of the design.

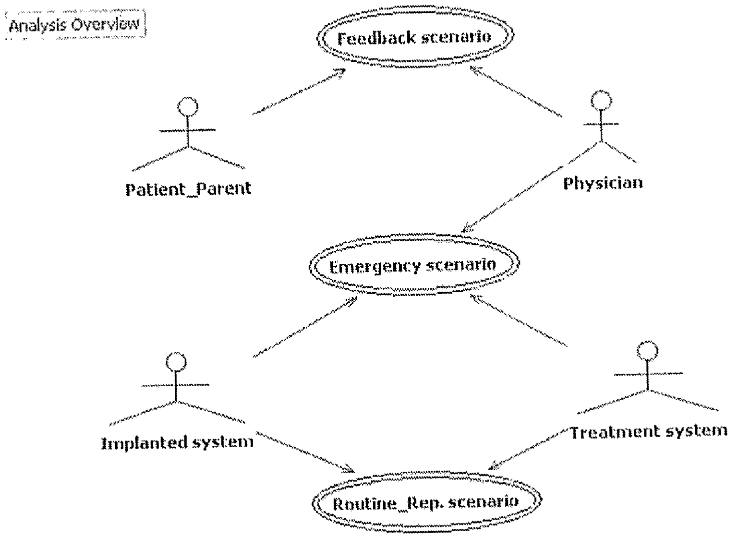



FIGURE 9.3: Initial Analysis Overview Diagram.

#### 9.3.1.1 Goal Specification

The initial set of goals for the proposed self diagnosis shunting system is:

- Analyse daily implanted shunt diagnosis report which would be received from implanted shunting system wirelessly via wireless transceiver.
- Analyse daily patient feedback which would be collected based on expert system.
- Read and analyse the historical shunt diagnosis database.
- Request ICP monitoring report from hydrocephalus treatment system.
- Communicate with hydrocephalus treatment system in order to update valve schedule or to send any shunt diagnosis history information.
- Access diagnosis/ feedback and treatment databases for reading or writing.
- Deal with any emergency request from implanted shunting system or physician.

- Take an immediate action when a need arises such as:
  - Enable/disable closed loop system.
  - Open/close the valve.
  - Turn On/off the ICP sensor.
  - Turn On/off the flowmeter.
  - Call physician or patient.
  - Change valve schedule.

#### 9.3.1.2 Functionalities

The functionalities of proposed intelligent agents system are illustrated where six functions were defined; feedback management, emergency cases management, report analysis, fault detection, decision making and diagnosis database management.

All these functionalities have been designed in PDT tools and configured as role. Figure 9.4 illustrates these roles with their corresponding percepts and actions.

#### 9.3.1.3 Scenario Development

Developing scenarios is one of the convenient ways that show the sequence of steps that take place within the system. Scenarios become even more important in the case of community-managed resources that are shared among many agents. They are used primarily to illustrate the normal running of the system and it also can be useful when used to indicate what is expected to happen when something goes wrong. Below are the fully developed steps for the scenarios that are expected to happen in the proposed intelligent system. Five scenarios were developed; feedback management, emergency cases, fault detection , diagnosis database management

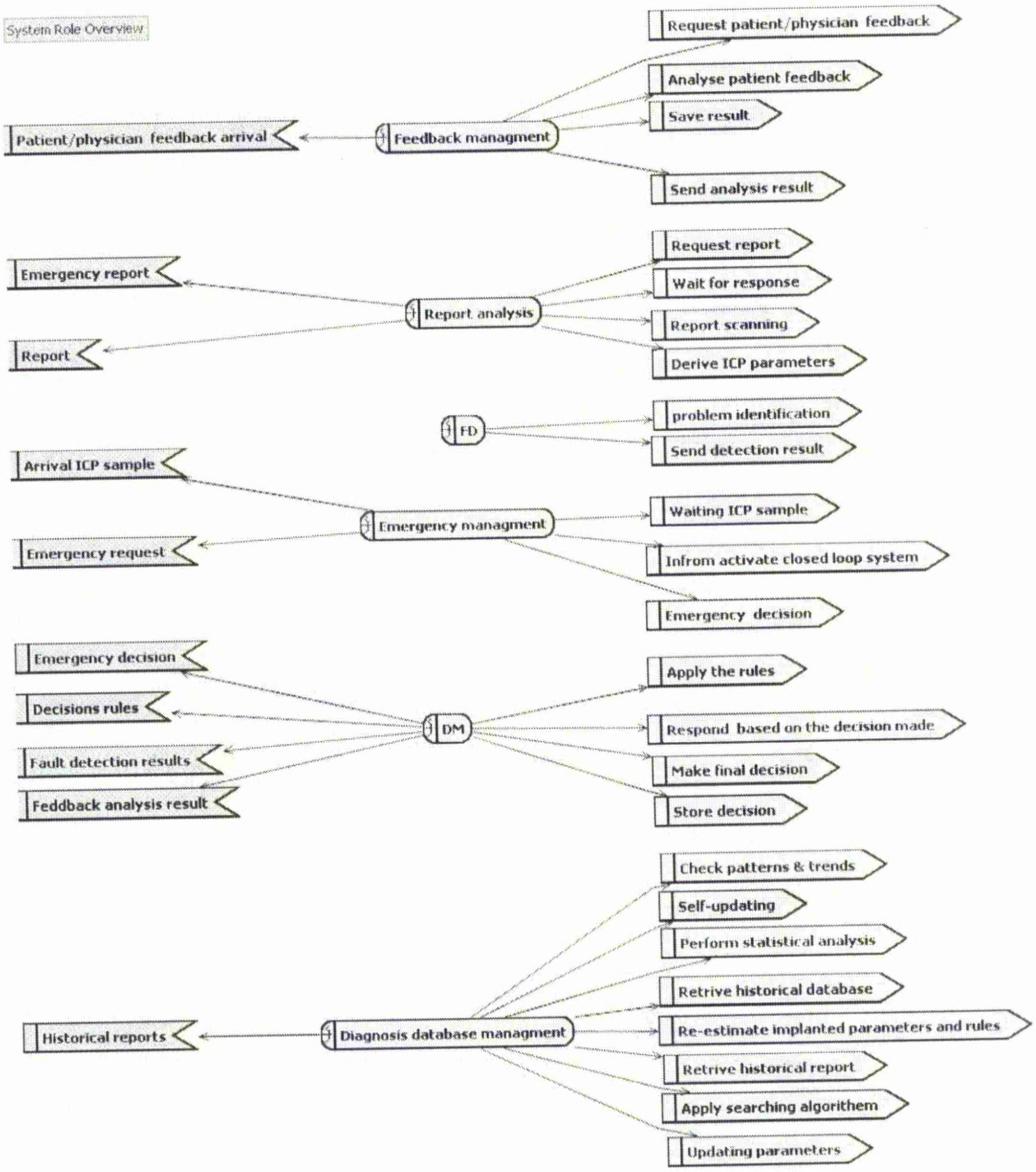



FIGURE 9.4: System roles overview (Fd:-Fault Detection, DM:-Decision Making.

and decision making. The steps and sequences of these scenarios are illustrated in Figures 9.5- 9.9 respectively.

All previous scenarios have been developed using PDT tool. Figure 9.10 illustrates the developed of feedback management scenario.

| Number | Step Type | Name | Role | Data used and produced |
|---|---|---|---|---|
| 1. | Goal | Derive a knowledge form feedback | Feedback management | |
| 2. | Action | Request feedback | Feedback management | |
| 3. | Action | Waiting for response | Feedback management | |
| 4. | Percept | Feedback arrival | Feedback management | feedback |
| 5. | Action | Analyse feedback | Feedback management | patient feedback |
| 6. | Action | Save result | Feedback management | Analyses result |
| 7. | Action | Send analysis result | Feedback management | Analysis result |

FIGURE 9.5: Feedback management Scenario.

| Number | Step Type | Step | Functionality | Data used and produced |
|---|---|---|---|---|
| 1. | Goal | Manage all emergency cases | Emergency management | |
| 2. | Percept | Emergency report | Emergency management | Report |
| 3. | Percept | Emergency request | Emergency management | message |
| 4. | Action | Inform activate closed loop system | Emergency management | message |
| 5. | Action | Request ICP sample | Emergency management | ICP & flow |
| 6. | Action | Wait the sample | Emergency management | |
| 7. | Action | Drive ICP and flow parameters | Emergency management | ICP readings Valve flow rate |
| 8. | Action | Follow fault detection scenario | Emergency management | |
| 9. | Action | Store result | Emergency management | Result |
| 10. | Action | Send result | Emergency management | Result |

FIGURE 9.6: Emergency cases scenario.

### 9.3.2 Architectural Design

The next stage is the architectural design where all internal composition of the system is specified. The architectural design phase uses artifacts produced in the system specification phase to determine what agents will be included in the system and the interaction between these agents. Architectural design of a system consists of three aspects; deciding on the agent types, describing the interaction between agents and designing the overall system structure.

| Number | Step Type | Step | Functionality | Data used and produced |
|---|---|---|---|---|
| 1. | Goal | detect and classify shunt faults | Fault detection | |
| 2. | Action | Request ICP and flow report parameters | Fault detection | |
| 3. | Other | Waiting for response | Fault detection | |
| 4. | Percept | Arrival requested Report | Fault detection | |
| 5. | Action | Report scanning | Report analysis | |
| 6. | Action | Drive ICP and flow parameters | Report analysis | ICP readings Valve flow rate |
| 7. | Action | Problem identification | Fault detection | feedback |
| 8. | Action | Store result | Fault detection | Result |
| 9. | Action | Send result | Fault detection | Result |

FIGURE 9.7: Fault detection scenario.

| Number | Step Type | Step | Functionality | Data used and produced |
|---|---|---|---|---|
| 1. | Goal | Check historical patterns | Diagnosis DB management | |
| 2. | Action | Apply searching algorithm | Diagnosis DB management | Algorithm |
| 3. | Other | Waiting for response | Diagnosis DB management | |
| 4. | Action | Respond based on decision made | Diagnosis DB management | |
| 5. | Action | Update DB | Diagnosis DB management | |

FIGURE 9.8: Diagnosis database management scenario.

The deciding on the agent type's aspect was achieved by three steps. First step is grouping the functionalities into agents. Second step is reviewing coupling by using agent acquaintance diagrams and deciding on the best grouping. A number of issues must be considered in determining how to group roles into agents, including standard software engineering issues of cohesion and coupling. The relationships of roles to data are also considered in determining role grouping.

Once decisions have been made about how roles are grouped into agents, information can be propagated from the role specifications, to show which percepts and actions are associated with which agents. This information is automatically generated into system overview diagram which provides an overview of the internal

| Number | Step Type | Step | Functionality | Data used and produced |
|---|---|---|---|---|
| 1. | Goal | Make a decision | Decision making | |
| 2. | Percept | Fault detection result | Decision making | |
| 3. | Percept | Patient feedback result | Feedback management | Feedback analysis result |
| 4. | Action | Apply the rules | Decision making | rules |
| 5. | Action | Send emergency message to treatment system | Decision making | message |
| 6. | Action | Send a message to display diagnosis result | Decision making | Message (Shunt state, fault type, fault time) |
| 7. | Action | Send a message to treatment system | Decision making | Message to advice (Modify valve schedule, monitoring...) |
| 8. | Action | Send a message to weaning system | Decision making | Message to advice (reducing shunt dependence) |
| 9. | Action | Save diagnosis result | Decision making | Local database, Global database, Shunt diagnosis database |
| 10. | Action | Send a message to patient, physician | Decision making | Advice (Urgently shunt revision, need monitoring for short time ) |

FIGURE 9.9: Decision making scenario.

system architecture. Figure 9.11 illustrates the system overview diagram of the self diagnosis multi-agent system for hydrocephalus shunting system.

To complete this overview, the definition of interactions between the agents protocols and adding any shared data is essential. In order to link agents with the appropriate protocols, the protocol structure is specified. The structure of message flows is specified using a textual notation for describing a modified AUML2 protocol specification. Links are created between agents and protocol symbols, based on the specification. This often provides a better understanding of a conversation structure than showing only messages between agents. Figure 9.12 presents a samples of Agent Unified Modeling Language 2 (AUML-2) code which was used to configure all communication protocol between the agents in the proposed system. Interaction diagrams, like use cases, give only a partial picture of the system's

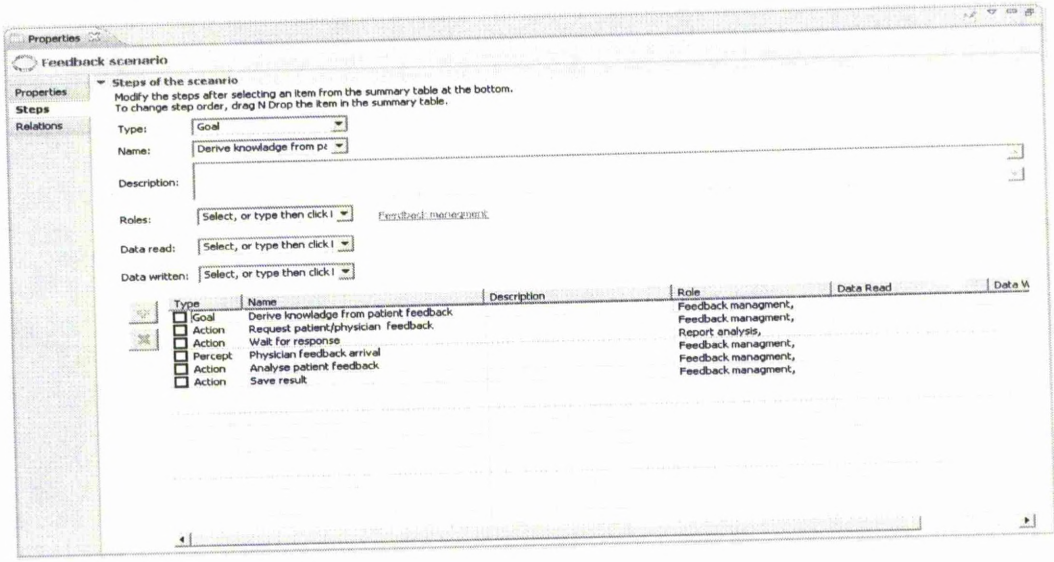



FIGURE 9.10: Implementation of feedback management scenario.

behaviour. In order to have a precisely defined system, it was progressed from interaction diagrams to interaction protocols which define precisely interaction sequences. The AUML notation was used to specify protocol. Consistency checking should be done between protocols and interaction diagrams, the system overview diagram, and use cases. Figures 9.13-9.17 shows AUML for the protocols which are developed in this system.

### 9.3.3 Detailed Design

In detailed design phase, the agents interact to achieve the goals associated via their roles and associated goals. A generic detailed design describes agents in terms of capabilities, or modules. These capabilities are then finally specified in terms of plans and events, which are of necessity more specific to the implementation paradigm or platform, than the preceding steps. At this point the abstract design of the system was complete, since the structure, the functions and the internal design had been reached.

At the end of the design process the system is ready for implementation. The implementation should be the next step in future work. The future work would implement, test and evaluate such system.

## 9.4 Discussions and Conclusions

The fact that intelligent agents are more and more present in the fault detection and isolation area is undeniable. This work propose one of the promising methods for self-diagnosis and monitoring of hydrocephalus implanted shunting system based on multi-agent approach. The multi-agent system is composed of different agents co-operating and communicating via message exchange to ensure the diagnosis process. The notion of a self-diagnosis multi-agent system has been presented along where are the benefits that are to be gained from this particular approach. In addition, the specific agent architecture along with the internal workings of each agent has been discussed and commented as well as the method of communication between the agents. In the proposed system, negotiations between different presented agents help the system to improve detection and isolation results by giving early warning and efficient decision. The proposed system would use intelligent techniques such as fuzzy logic and expert system to perform the required functions. Real-time shunt components testing and monitoring seem to be the most promising way to decrease the number of shunt revision, then reduce suffering of hydrocephalus patient. The implementation of the proposed multi-agent self-diagnosis system will provide a desirable autonomy in terms of self-diagnosis and monitoring the implanted components of the shunting system. The treatment of hydrocephalus would be improved by applying such diagnosing system. The proposed intelligent diagnosis system is now under development using a Java-based interpreter for an extended version of AgentSpeak called Jason.

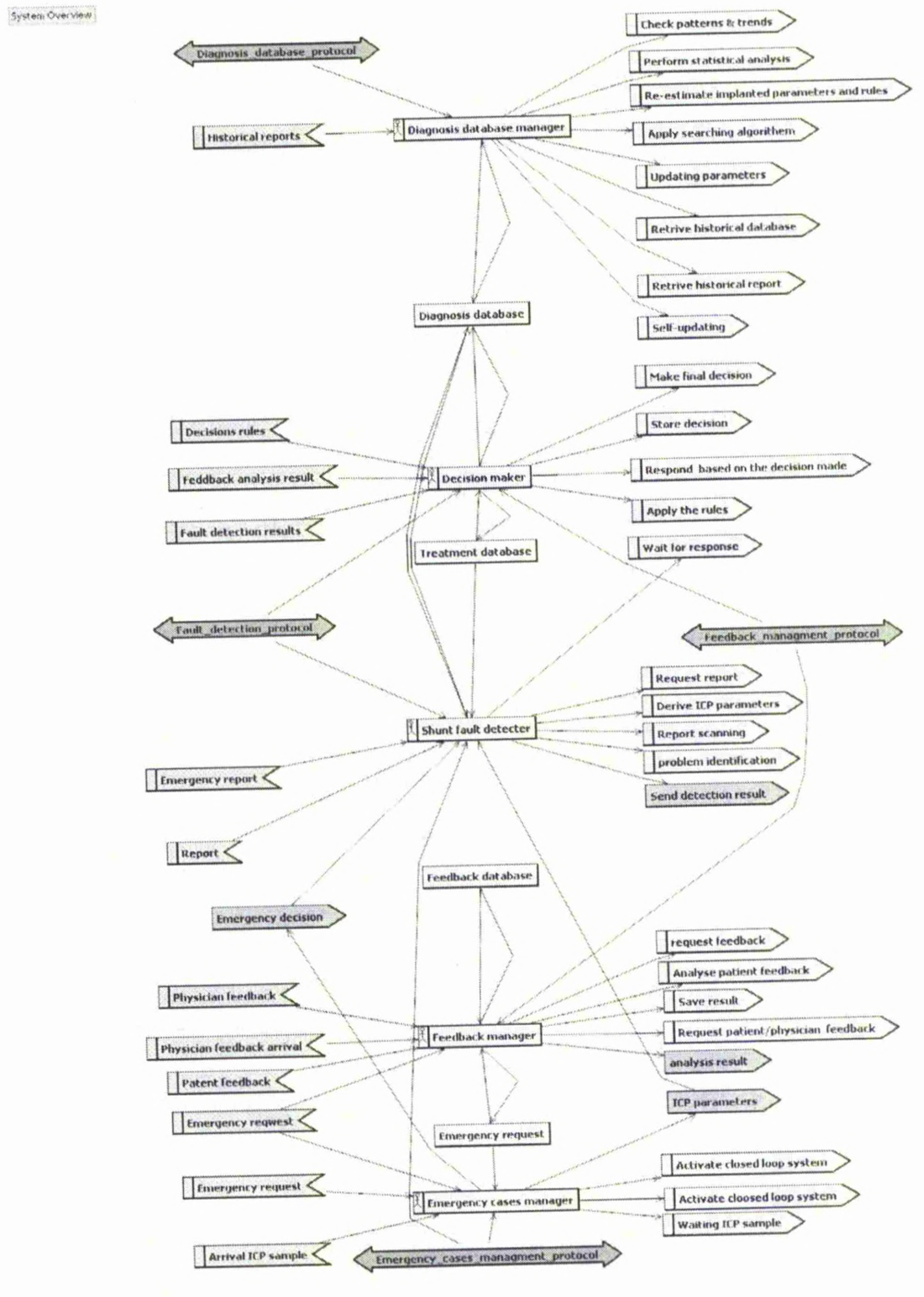



FIGURE 9.11: System overview diagram.

```
#AUML text notations:
start Fault_detection_protocol
# short name declarations:
actor TR  Treatment system
# //actor PH physician
agent FD Shunt fault detecter
agent DM Decision maker
# Interaction definitions:
box alternative
percept TR FD  Report
    message FD DM Send detection result
next

action  FD TR Request report

percept TR FD  Report
message FD DM Send detection result
 end alternative

finish

#AUML text notations:
start Feedback_managment_protocol
# short name declarations:
actor PA  patient
actor PH physician
agent FBM Feedback manager
agent DM Decision maker
# Interaction definitions:
box alternative
percept PA FBM Patent feedback
next
percept PH FBM Physician feedback
next
action FBM PA request feedback
percept PA FBM Patent feedback
next
action FBM PH request feedback
percept PH FBM Patent feedback
```

```
#AUML text notations:
start
Emergency_cases_managment_protocol
# short name declarations:
actor PA  patient
actor PH physician
actor TR Treatment system
agent FBM Feedback manager
agent ER Emergency cases manager
agent FD Shunt fault detecter
# Interaction definitions:
box alternative
percept PA FBM Emergency reqwest
next
percept PH FBM Emergency reqwest
next
percept TR ER Emergency reqwest
end alternative

    action ER TR  Activate cloosed loop
system
 action ER TR  Waiting ICP sample
 message ER FD ICP parameters


 message ER FD Emergency decision

 #AUML text notations:
 start Diagnosis_database_protocol
 # short name declarations:
 actor TR  Treatment system
 # //actor PH physician#
 agent DDB Diagnosis database manager
 # agent DM Decision maker
 # Interaction definitions:
 # box alternative
  action  DDB TR   Updating parameters

 finish
```

FIGURE 9.12: AUML communication protocol code.

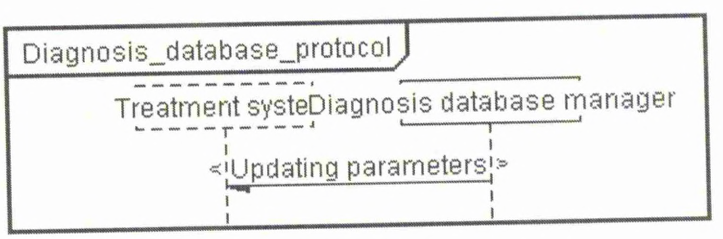



FIGURE 9.13: Diagnosis database protocol.

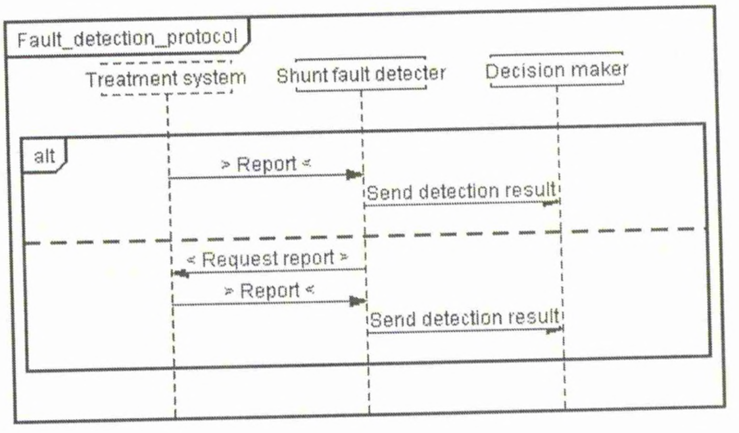



FIGURE 9.14: Fault detection protocol.

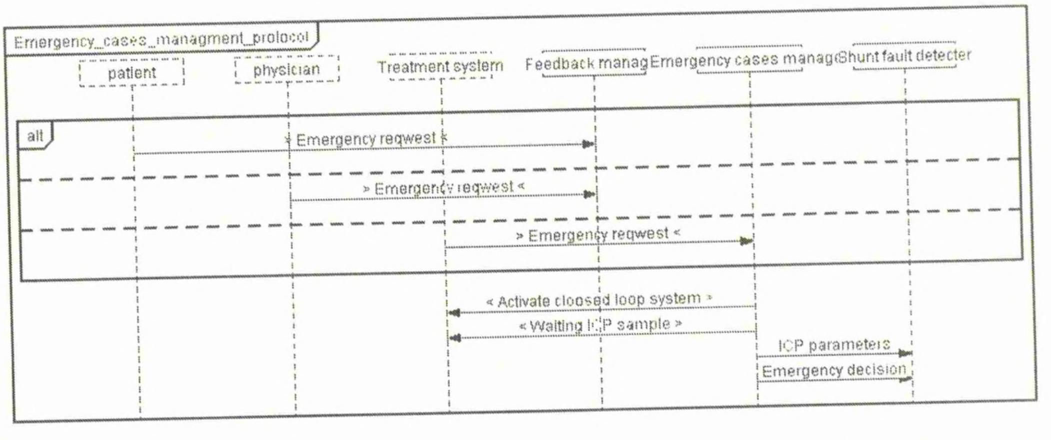



FIGURE 9.15: Emergency cases management protocol.

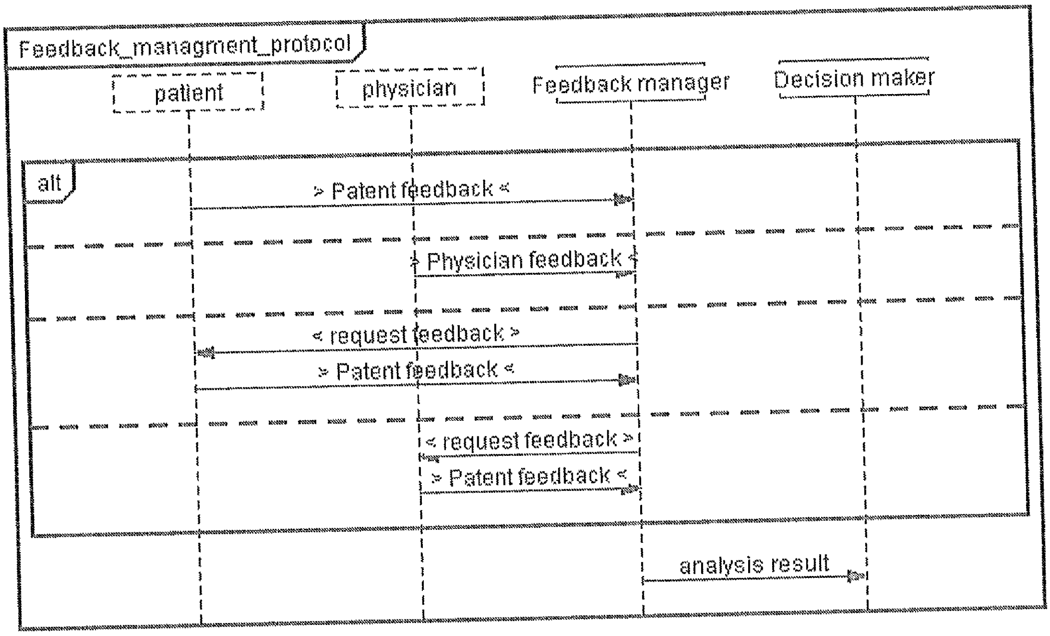



FIGURE 9.16: Feedback management protocol.

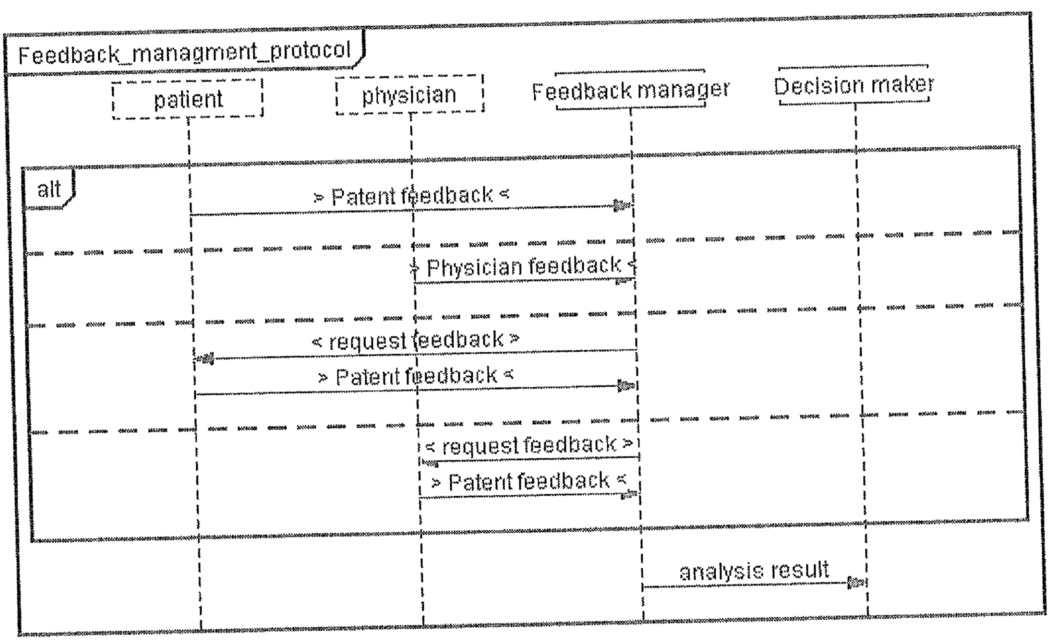



FIGURE 9.17: Decision making protocol.

# Chapter 10

# Test and Evaluation

## 10.1 Introduction

The implantable shunting system was designed, simulated and tested to carry out many tasks that were covered in previous chapters such as regulating the mechatronic valve, collecting ICP readings, analysing these readings, generating short and long reports and responding to all emergency cases. On the other hand, the external shunting system was designed, simulated and tested to perform its functions in managing hydrocephalus and diagnosing the whole shunting system such as updating valve schedule, wirelessly controlling the valve status, requesting ICP data and flow measurements.

To assess the functioning of the whole shunting system (hydrocephalus management and shunt diagnosis) and in order to evaluate its performance, a prototype of the intelligent shunting system (implantable and external) is needed. This would urge the need for a dynamic environment that simulate the intracranial hydrodynamics of hydrocephalus patient and responds to any change in the valve status. Such environment can be either physical (a prototype) or computer-based (mathematical) model. There are many challenges facing the development of a physical prototype of intracranial hydrodynamics. The main challenges are the high sampling rate of the real ICP signals and generating ICP wave that is equivalent to clinical signal.

In this chapter, a prototype of hydrocephalus shunting system (implanted and external) is illustrated and integrated with an embedded management and diagnosis software. Momani *et al.* [75] have simulated a cerebrospinal fluid (CSF) hydrodynamics model using Simulink for both normal and shunted high pressure hydrocephalus conditions to study the performance of a mechatronic shunt. Such system is used to provide an interactive dynamic environment for the proposed prototype. In addition, the interfacing between the implantable prototype and intracranial hydrodynamics model is needed to exchange input/output data, as well as to control the mechatronic valve and ICP sensor.

The external part of this prototype is integrated with an embedded external management and diagnosis system. This system was built using high level tools and languages such as, Jason for agent software, fuzzy logic tools, Prolog and java languages. The interfacing between the external part and shunt management software is achieved by using serial interface in order to transfer the data between such software and the prototype.

A bidirectional wireless management shunting protocol which was illustrated in Chapter 3 was used to establish the communication between the external and implantable prototypes. This protocol was used to enable them communicating and interacting.

The structure of this chapter starts with a literature survey, where a brief background about the physical and computer-based intracranial hydrodynamics models and interfacing with microcontroller were explored. As a result, the researcher proposes a physical model which is suitable for a mechatronic shunt environment and can be integrated with the proposed mechatronic shunting system. In addition, Momani model [75] has been introduced, and then interfacing of such model with implantable prototype was illustrated. As well as an interfacing of the external prototype with a PC has been presented. Then, wireless protocol was used to make a bridge between the two subsystem's prototypes. At the end of this chapter, the proposed shunting design, management and treatment methods and and diagnosis methods were evaluated, tested and validated by considering some cases such as shunt diagnosis, valve schedule updating and the power consumption algorithm.

## 10.2 Literature Review

### 10.2.1 Physical Intracranial Hydrodynamics Model

Taylor *et al.* [109] had used a model for the CSF circulation incorporating increased resistance to CSF outflow [24 mmHg/(ml/min)] and decreased hydrodynamic compliance (<2 ml/mmHg), that are typical conditions in hydrocephalus to test nine of the most commonly used types of hydrocephalus valves. Their aim was to document the pressure response to constant rate infusion of a model of CSF circulation with different valves and to define which measures are useful in shunt testing in vivo. They concluded that the infusion test is able to assess shunt function. End-equilibrium pressure recorded during the test has been confirmed to correlate with the shunt's performance.

Czosnyka *et al.* [24] have proposed a new lumped-parameter compartmental model of CSF and blood flow in healthy subjects during the cardiac cycle. The system was divided into five submodels representing arterial blood, venous blood, ventricular CSF, cranial subarachnoid space, and spinal subarachnoid space. These submodels are connected by resistances and compliances. The model developed was used to reproduce certain functional characteristics observed in seven healthy volunteers, such as the distribution (amplitude and phase shift) of arterial, venous, and CSF flow. The results showed a good agreement between measured and simulated intracranial CSF and blood flow.

Drake [30] had presented a physical intracranial hydrodynamics model that was used for shunt testing. A pump was used as a source of pressure, *e.g.* constant displacement (syringe and peristaltic) pumps are most commonly used in medical laboratories. Coordinating the test sequence and recording data is best done by an automated, preferably computerised, system. Such a system requires microcontroller to command and receive transducer's readings. An accessory (mechanical, electronic or computer controlled) device may be added to produce pressure pulses. There are various clinical techniques to assess shunt functioning in *vivo.* A laboratory shunt testing methodology (UK Shunt Evaluation Laboratory) has been established from a group of Academic Neurosurgical Unit, Addenbrookes's Hospital, Cambridge, UK to evaluate the result of an infusion test in a physical model of the hydrocephalus. The components of this physical model are shown in Figure 10.1 . A pump had been used in this model to help represent a CSF under normal conditions. A pulse pressure generator also used to solve the high sampling rate problem of the ICP signal (100-125Hz) [29].

Another group from Academic Neurosurgical Unit, Addenbrookes's Hospital, Cambridge, UK had presented another simple physical model of CSF (shown in Figure 10.2). This model is nearly similar to the previous model. This was used to represent CSF production and circulation. In addition eleven different hydrocephalus shunts were tested using this model. Most physical properties of CSF were taken into consideration in this study [28].

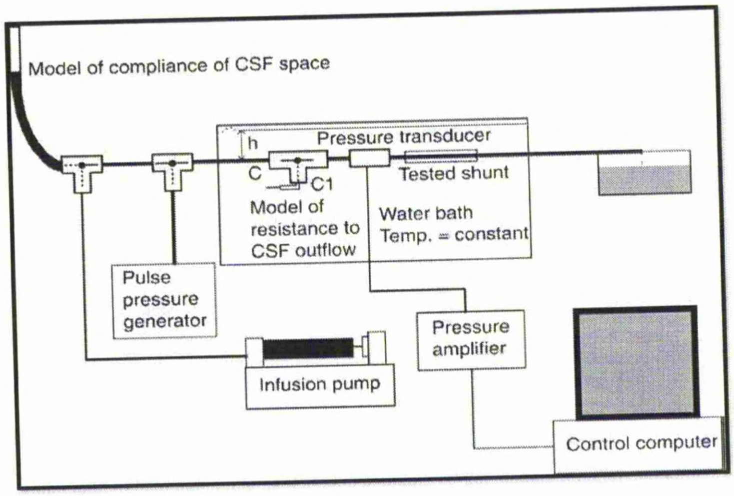



FIGURE 10.1: The components of UK Shunt Evaluation Laboratory physical model according to [29].

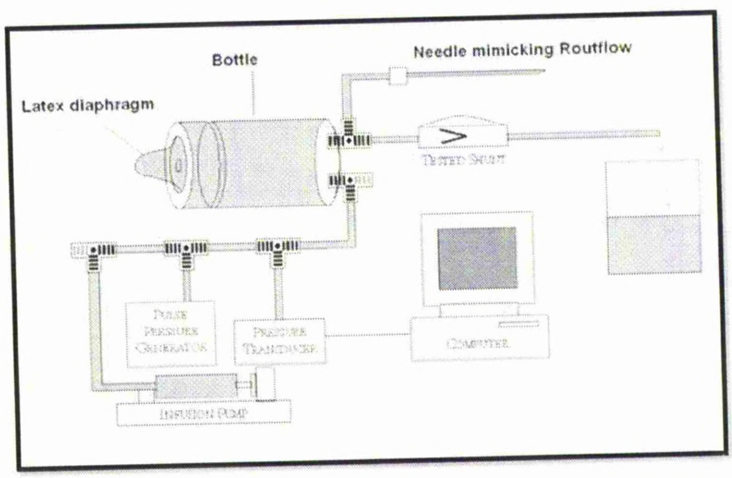



FIGURE 10.2: Schematic diagram of the testing physical model according to [28].

### 10.2.2 Computer-Based Intracranial Hydrodynamics Model

In recent decades, a large number of mathematical models have been proposed to explain, test and evaluate the shunting system. Momani *et al.* [75] have simulated a cerebrospinal fluid (CSF) hydrodynamics for both normal and high pressure hydrocephalus conditions to study the performance of a mechatronic valve. Furthermore, they simulated two types of existing valves along with the mechatronic valve controlled by different controlling paradigms, namely, scheduled and closed-loop. In addition, the effect of such systems on the intracranial hydrodynamics was investigated using numerical simulations. Figure 10.3 shows the block diagram of this model [75].

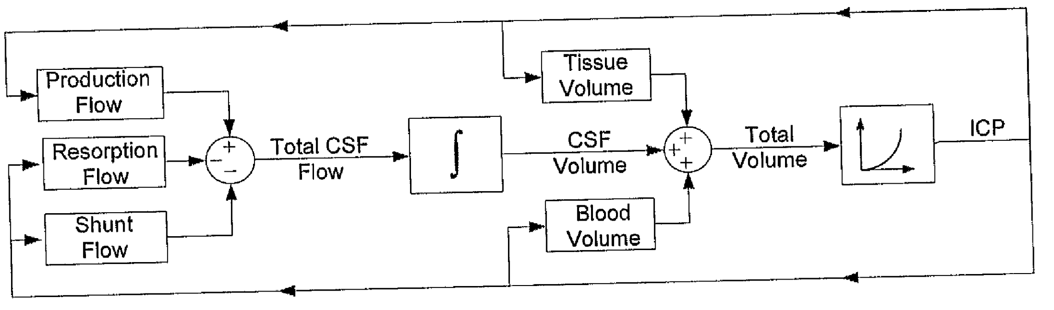



FIGURE 10.3: The block diagram of Momani model [75].

### 10.2.3 Interfacing with Microcontroller

Li et al. [57] have presented an approach to endow the microcontroller with GUI capabilities by interfacing it with Matlab and by exploiting Matlab's abundant GUI tools. The proposed Matlab-based GUI environment for microcontroller relies on the use of serial communication between the microcontroller and a personal computer. In addition they had presented three examples to illustrate data communication between BS2 microcontroller and Matlab thus to demonstrate the efficacy of their approach. They also had addressed the issue of importing GUI capabilities to the MIC by combining powerful software, namely, Matlab, with microcontroller. As a result, they had concluded that their approach can be applied to any microcontroller that supports serial communication.

Rebeschielj [93] had presented a new tool box "MIRCOS" (MIcrocontroller-based Real time Control System) for graphical programming and real time operation of a standard 16-bit microcontroller 80C166 using Matlab and Simulink. With this toolbox, rapid control prototyping is possible on this widely available hardware.

The system can also be used for Hardware-in-the-Loop Simulations. The complete controller synthesis, the automatic generation and implementation of the control program on the microcontroller, and the control task itself can be carried out under Matlab's comfortable user interface. Furthermore, the full functionality of Matlab and Simulink can be used in MIRCOS, for instance, for parameter hand-off or visualisation without interrupting or impeding the control task running on the 80C166. In addition, via this toolbox the control program is automatically generated from a Simulink structogramm and programmed on the MIC. By means of Matlab and Simulink, which run on the host PC in parallel, it is possible to do user inputs, parameter changes and visualisation of measurement data. They also used RS232 serial interface for communication between PC and microcontroller. As a result, exchange data between PC and MIC had been done using three Simulink blocks via such interface.

Ferencz *et al.* [52] had demonstrated the strength of National Instruments hardware and software technology in a situation where it is important to build a heterogeneous environment with the need of simulation, prototype test, field measurements and production test. Since the same environment was used in different places in the R&D process, it speeds up the development and cuts back the costs. The ability to develop and tune control algorithms without being connected to the real controlled system or not using the prototype controller which might not even exist at an early phase, opens a great opportunity for concurrent engineering especially in a virtual company. The fact that the simulation of the controlled system can be developed both in LabView and Matlab environment helps to reduce the time of the specification for the customers since it is possible to use their model of the system that is required to be controlled. They also had sketched a block diagram of interfacing the PC computer via RS 232 interface with the National

Instruments kit.

Kapila *et al.* [50] had presented a Matlab and Simulink based software platform that enables the use of inexpensive microcontrollers for data acquisition and control tasks. The proposed framework is well suited for data acquisition and control tasks that require graphical user interface (GUI) and/or advanced computational capabilities but do not require stringent hardware performance. They had illustrated the efficacy of their data acquisition and control technique by performing position control of a DC motor using a Basic Stamp 2 (BS2) microcontroller and their Matlab data acquisition and control toolbox. In addition, they had developed a low-cost PC-based DAC board using Parallax Inc.'s BS2 microcontroller. Furthermore, they had produced a library of BS2 functions for Simulink. Next, they had exploited Simulink's icon-based programming environment to implement user-defined algorithms in a block diagram format. Also, they had build upon the foundation which used to exploit Simulink and Matlab's built-in serial communication capabilities to communicate with various sensors and actuators connected to a BS2 microcontroller.

## 10.3 Proposed Physical Model

Due to the fact that the mechatronic valve is under investigated and based on literature review and the the researcher's knowledge, a hydrocephalus physical model that can be used to evaluate the performance of mechatronic shunting system is not available. This motivate the researcher to study the ability of proposed such physical model. Based on the design of the proposed mechatronic shunting system, the researcher has proposed a physical intracranial hydrodynamic model to assess, test and evaluate such shunting system. The proposed system would be suitable for testing and evaluating the functions of the mechatronic shunting system. This model is illustrated in Figure 10.4 and it would be mainly composed of the following components:

- Micro pump with average flow 0.28-0.33 ml/min.
- Container of special shape to simulate the exponential relation between ICP and total volume of CSF (ICP = $Ae^{BV}$).
- Mechatronic valve (electronic or hydraulic valve) with different resistances.
- Pulse pressure generator that would be used to generate the ICP pulses.
- Needle to mimic the natural drainage of CSF from the brain.
- ICP transducer to collect the ICP signals.
- Flowmeter to measure the flow change through the valve when it is open.
- Texas Instruments kit to receive the ICP readings, analyse and make a decision regarding regulation of the valve.
- Implanted shunt software to regulate the valve and collect ICP readings.
- Stepper motor to control the angle between the CSF tank and the valve to mimic the change in the patient posture *i.e* erect, recumbent at different angle.

Such proposed model would be suitable environment to evaluate, test and validate most of the proposed methods and design of the mechatronic shunting system.

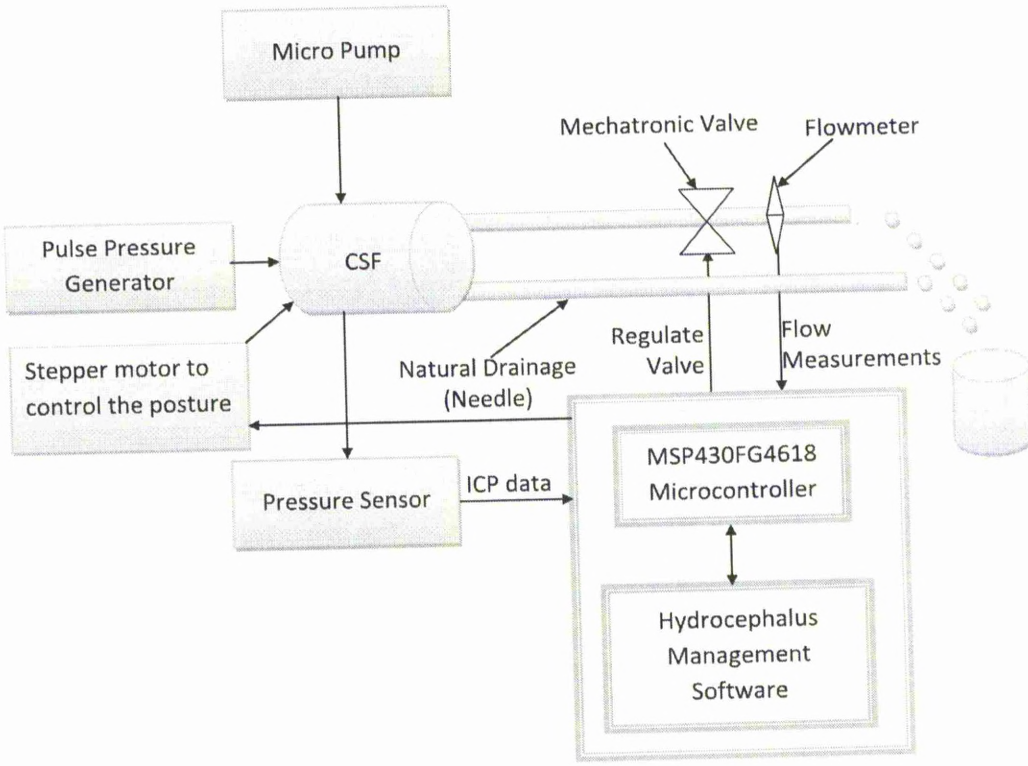



FIGURE 10.4: The proposed physical model.

## 10.4 Methodology and Experimental Work

The aim of this study is to provide a systematic method to test the performance of the proposed shunting system. Therefore, it was decided to follow a prototype-based methodology to support the proposed design methods in hardware and software cases. The experimental work includes five procedures: (1) identify the hardware and software components, (2) interface the implanted shunting prototype with hydrocephalus patient model, (3) interface the external shunting prototype with management and treatment shunting software, (4) interface between the two shunting prototypes using bidirectional wireless management shunting protocol, and (5) finally test and evaluate the intelligent shunting system prototype by applying various proposed functions such as shunt diagnosis, valve schedule updating, request a report from implanted part, and activate closed loop option and emergency cases.

### 10.4.1 Interactive Environment

Developing a comprehensive computer-based model that mimic the behavior of the hydrodynamics in case of high pressure hydrocephalus patients (non shunted and shunted) is an important milestone in understanding hydrocephalus and in evaluating current and future treatments. To predict the performance of the proposed shunting system, a model of intracranial hydrodynamics was conceptualised and simulated mathematically and numerically. In this prototype, Momani model [75] is used as a test environment. Thus, the effect of varying the parameters of the proposed system on the intracranial hydrodynamics can be monitored in real time.

### 10.4.2 Implanted and External Prototypes

Texas Instruments' TRF6901with MSP430 evaluation kits have been used to prototype the implantable and external shunting systems. The Texas Instruments TRF6901 is a low-cost RF transceiver that is intended for use to establish a frequency-programmable, halfduplex, bidirectional RF link (902 MHz to 928MHz) in the European or North American industrial, scientific, and medical (ISM) bands. The kit was used in two modes which are stand alone mode and system mode. In addition, MSP430FG4618/F2013 experimenter's boards were used in this prototype. The MSP430FG4618/F2013 experimenter's board is a comprehensive development target board that can be used for a number of applications. The MSP-EXP430FG4618 kit comes with one MSP430FG4618/F2013 experimenter's board and two AAA 1.5 V batteries. The MSP430FG4618/F2013 experimenter's board is based on the Texas Instruments ultra-low power MSP430 family of microcontrollers [79],[80]. Wireless communication is possible through the expansion header which is compatible with a Chipcon Wireless Evaluation Modules from Texas Instruments. Interface to a 4-mux LCD, UART connection, microphone, audio output jack, buzzer, and single touch capacitive touch pad enable the development of a variety of applications. Communication between the two on-board microcontrollers is also possible. In addition, all pins of the MSP430FG4618 are made available either via headers or interfaces for easy debugging. LEDs are also available in this board and they were used to test and evaluate a valve control schedule. Furthermore, a serial interface also is supported in such board to give the ability of interfacing it with any other external device. The implantable shunting software that was covered in previous chapters was embedded into the microcontroller on one of the boards by using IAR embedded workbench. On the other side, the external shunting software was embedded into patient device which was replaced by a PC in this work.

### 10.4.3 Interfacing of Hydrocephalus Patient Model with Implanted Prototype

Due to the complexity of the proposed shunting system, assessment, testing and evaluation would mainly be based on Momani intracranial hydrodynamics (ICH) model [75] as a source of the ICP readings as well as an interactive environment to test, evaluate and validate the valve regulation method. The microcontroller was used to receive the ICP data from the output of the intracranial hydrocephalus (ICH) model via RS232 interface, and then store it in RAM. A specific ICP sensor schedule was used to collect ICP samples. The ICP data was analysed by the intelligent analyser subroutine and the results were passed to valve management subroutine. The valve management subroutine send the decision, *i.e.* either open or close the valve, back via RS232 to the ICH model. The valve in the intracranial hydrodynamics model was regulated based on both analysis decision and valve schedule which were stored into RAM. Simultaneously, the ICP level will be affected by the decision and will be sent again to the microcontroller. The RS-232 standard defines the two devices connected with a serial cable as the Data Terminal Equipment (DTE) and Data Circuit-Terminating Equipment (DCE). This terminology reflects the RS-232 origin as a standard for communication between a computer terminal and a device. Figure 10.5 illustrates the sequence of this method.

Serial ports mainly consist of two signal types: data signals and control signals. To support these signal types, as well as the signal ground, the RS-232 standard defines a 25-pin connection. However, most Windows and UNIX platforms use a 9-pin connection. In fact, only three pins are required for serial port communications: one for receiving data, one for transmitting data, and one for the signal ground. The pins and signals associated with the 9-pin connector are described in Table 10.1.

#### 10.4.3.1 Hardware Environment

The hardware environment for this part consists of a microcontroller, PC, and data link between the two. The microcontroller was used to run the embedded implanted shunting software. The PC is used to simulate the patient and to run the ICH model. The PC also serves as a hydrocephalus patient environment with mechatronic shunting system. Thus, the microcontroller would collect ICP data through serial connection from the patient model which is running in real time on the PC. The requested data is passed into RAM, stored and analysed based on the implanted embedded software requirements. A data link is also needed for the microcontroller and PC to communicate. The serial cable, which is used

TABLE 10.1: Description of pins and signals associated with the 9-pin connector

| Pin number | Label | Signal Name | Signal Type |
|---|---|---|---|
| 1 | CD | Carrier Detect | Control |
| 2 | RD | Received Data | Data |
| 3 | TD | Transmitted Data | Data |
| 4 | DTR | Data Terminal Ready | Control |
| 5 | GND | Signal Ground | Control |
| 6 | DSR | Data Set Ready | Control |
| 7 | RTS | Request to Send | Control |
| 8 | CTS | Clear to Send | Control |
| 9 | RI | Ring Indicator | Control |

in this prototype, is called the DB-9 serial cable. This cable links a serial, or COM, port on the PC to the serial port on the selected board. This allows the implanted software to collect ICP data from the ICH model. In addition, it would regulate the valve and control the pressure sensor that are simulated inside the ICH Simulink model.

#### 10.4.3.2 Software Environment

Serial communication is a low-level protocol used for data communication between two or more devices. As the name implies, serial communication uses a data port to send/receive data in a serial manner, *i.e.* one bit at a time. Programming two or more devices to communicate serially requires that the devices operate at the same communication rates. In this part, a data communication link was established between MSP430 board and a PC, where the PC hosts the hydrocephalus patient model and the microcontroller hosts the implantable shunt software. The software sections that were used in this operation are described below.

- Microcontroller Program

  The microcontroller is programmed using C programming language. The program start by initialising the UART interface to work either as send or receive direction, then an interrupt subroutine used to acquire any received character through the UART port. The internal UART can be configured simply using the special function registers and reading from or writing to the UART comes down to reading from or writing to a specific special function register. The baud rate can be either based on the crystal frequency or it can be specified using one of the timers. The received data was transferred to the configured received buffer ($R_x$). Then, the data was transferred from the $R_x$ buffer to be stored in specific memory location. The program would continuously run this task until the interrupt is stopped by other task. The MSP430 microcontroller can generate an interrupt on the following events: timer overflow, receiving transmitting a character via the serial port, or external events. An interrupt routine is the same as a normal sub-routine but it has to end with the RETI (return from interrupt routine) instruction instead of the RET (return from routine) instruction. The code of this program is enclosed in Appendix C.

- Matlab$^{TM}$ Program

  Matlab$^{TM}$ is a powerful software package that allows data plotting in multiple dimensions. Matlab$^{TM}$ versions 6.1 and higher support serial communication. Matlab$^{TM}$ also has built-in toolboxes that contain commonly used engineering functions. Matlab$^{TM}$ code was used in this operation to enable the ICH model to send /receive data from/ to microcontroller. The code, some pertinent commands and toolboxes are illustrated in Appendix C.

- Simulink

  Simulink is MathWorks' icon based programming toolbox [8] that allows the user to construct a block diagram representation of the system being studied. The user can insert block diagrams to specify input functions, system dynamics, controllers, filters, etc., in a Simulink model. The user can similarly specify how and where the output data is to be displayed by Simulink. The Simulink toolbox itself contains many libraries containing functions. The user inserts appropriate function in his/her Simulink block diagram by using a drag-and-drop procedure. The dials and gauges library of Simulink allows the system to insert control and display objects into a Simulink model. These objects allow the software to set system parameters and visualise system response.

A block diagram of the proposed implanted prototype is illustrated in Figure 10.5.

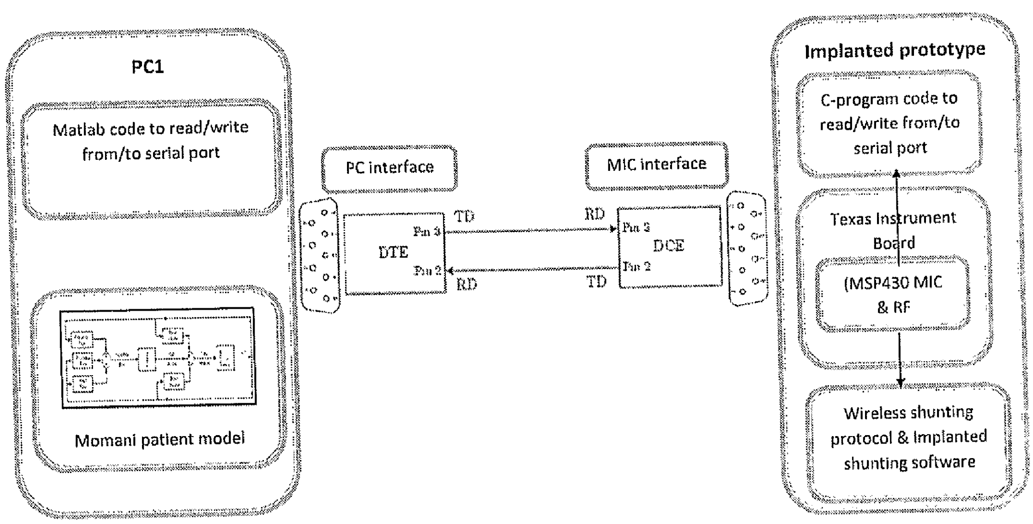



FIGURE 10.5: A block diagram of the proposed implanted prototype.

### 10.4.4 Wireless Shunting Protocol

The researcher has previously proposed a bidirectional wireless management protocol which is covered in Chapter 4. Such protocol would be able to perform a number of tasks, including regulating the mechatronic valve based on a dynamically modified time valve schedule and communicating between the two diagnosing subsystems. As well as remotely reprogramming implanted shunting system, request a daily report from implantable system and more. The next step is using this communication protocol to communicate between the two prototype parts (*i.e.* implanted and external). In this section, the implanted derived parameters, ICP data and other important shunt information were prepared and set into packet, and then this packet has been encrypted and wirelessly send through RF from implanted shunt to the external one. On the other side, the packet was received, decrypted and stored by the external prototype.

A block diagram of the communication method between shunting subsystems is illustrated in Figure 10.6.

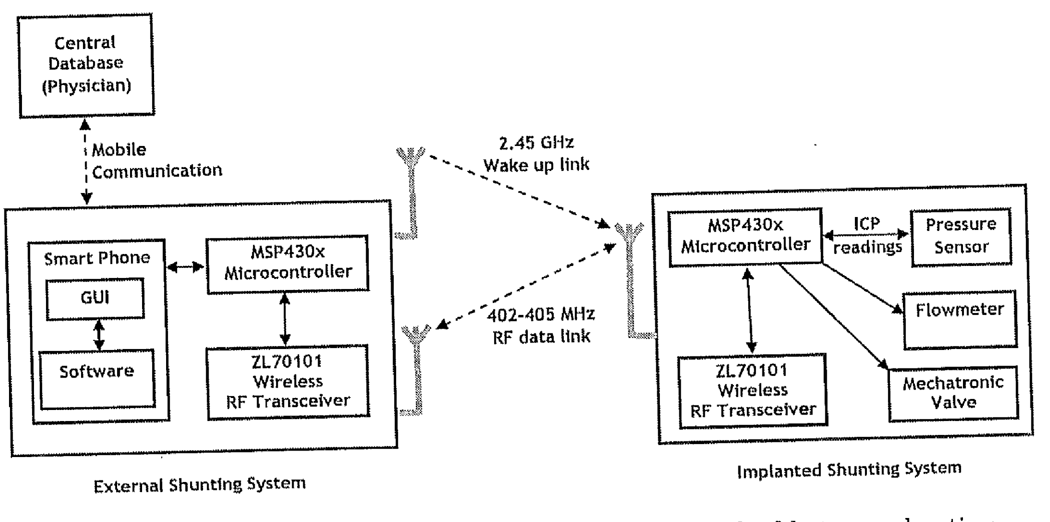



FIGURE 10.6: A block diagram of the communication method between shunting subsystems.

### 10.4.5 Interfacing between Shunt Management Software and External Prototype

The external shunting software is mainly consists of two parts. The first part is responsible for management and treatment of hydrocephalus by performing many tasks such as wirelessly auto valve schedule updating, request ICP data and parameters, deal with any emergency case, and activate closed loop mode. The second part is responsible for shunt management and diagnosis. Some of it's features are detecting and identifying any implanted shunt fault and dealing with such fault by contacting treatment software as well as the physician or the patient. This software would be embedded into the patient device that is replaced in this work by a PC.

To test and evaluate the performance of the shunting system based on the previous functions, an interface is needed between this software located on the PC and the external prototype. The external shunt prototype mainly consists of PC, microcontroller and transceiver. The microcontroller and transceiver are integrated into Texas instrument evaluation board. A data communication link is established between MSP430 board and a PC, where the PC hosts the external shunting software and the microcontroller hosts the external part of the wireless shunting protocol. The serial cable, which is used in this prototype, is called the DB-9 serial cable. This serial connection enables data communication between the external software and wireless shunting protocol.

A block diagram of the proposed external prototype is illustrated in Figure 10.7.

### 10.4.6 Results and Discussion

As a result of this work, a prototype of the shunting system is developed that mainly consists of two Texas evaluation boards, two RF transceivers, two serial

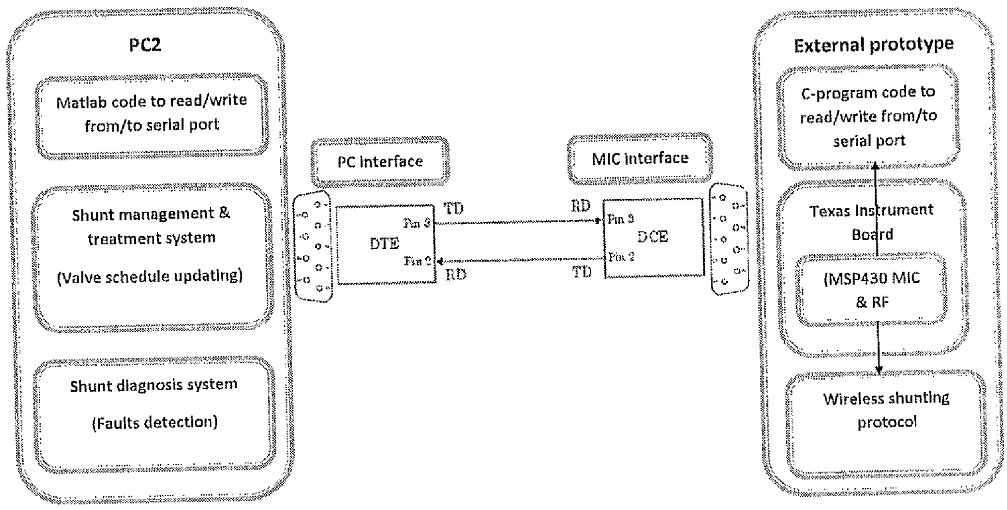



FIGURE 10.7: A block diagram of the proposed external prototype.

cables, batteries and two PCs. The first step of developing the prototype was testing the interface between the hydrocephalus patient model and the implantable prototype through serial port. The outcome of patient model (*i.e.* ICP data) was sent through serial port to microcontroller according to ICP sensor schedule which is also controlled by microcontroller through serial port. Then, the implanted embedded software stores, analyses the received data and share the result with other implanted subroutines. The second step was testing and evaluating the wireless communication protocol. A packet with ICP readings and derived parameters are prepared and wirelessly sent via RF to the external part. The received packet is then stored in external RAM. The third step was testing the interface between the external prototype and the management and treatment software. The stored data was read from external RAM and sent into PC through serial cable. Then, this data was passed to shunt software and used in treatment and diagnosis.

On the other hand, the treatment and diagnosis software was used to perform many tasks and then sending back various parameters to the implanted shunt software via serial port and through RF transceivers. These parameters were received by the implanted shunt software to update the current values for regulating the valve as well as collecting ICP data tasks. As a result of developing such prototype, power consumption algorithm and system's functions were tested as follow.

- Shunt Diagnosis and Faults Detection

  The fault detection and diagnosis of a mechatronic hydrocephalus shunting system has been illustrated in Chapter 6. In the proposed diagnosis system, a Simulink set-up was constructed in order to build the rule base of the shunt faults diagnosis system. It also served to detect the faults while the patient model was running under various faults. In addition, such setup was utilised as a dynamic environment to evaluate the performance of the fuzzy logic fault diagnosis system. The Simulink set-up consists of a hydrocephalus patient model, a data pre-processing model and fuzzy logic controller. While the patient model is made up of intracranial hydrodynamics of hydrocephalus patient, a mechatronic valve, ICP sensor, flowmeter, and faults models.

  The developed shunt prototype was used to test and evaluate the performance of such system. The sequence of the evaluation is as follows,

  - The ICP data and flow measurements have been collected from intracranial hydrocephalus model which was running on $PC_1$.
  - This data has been transferred through serial cable into implanted prototype.
  - The wireless shunting protocol was used to transfer this data wirelessly from the implanted prototype into the external prototype.
  - The received data was transferred through serial cable from external prototype into $PC_2$ and then received by Matlab.

  - The pre-processing model used this data to derive the required parameters for the fault detection system such as mean ICP, mean absolute deviation and mean valve flow.
  - Finally the fuzzy logic diagnosis model used these parameters as input variables to detect and identify any fault.

This operation has been done successfully as required and the fuzzy logic system was used to detect various proposed faults with high accuracy based on the received ICP data and flow measurements. This evaluation has been achieved by using shunt prototype that is illustrated in Figure 10.8.

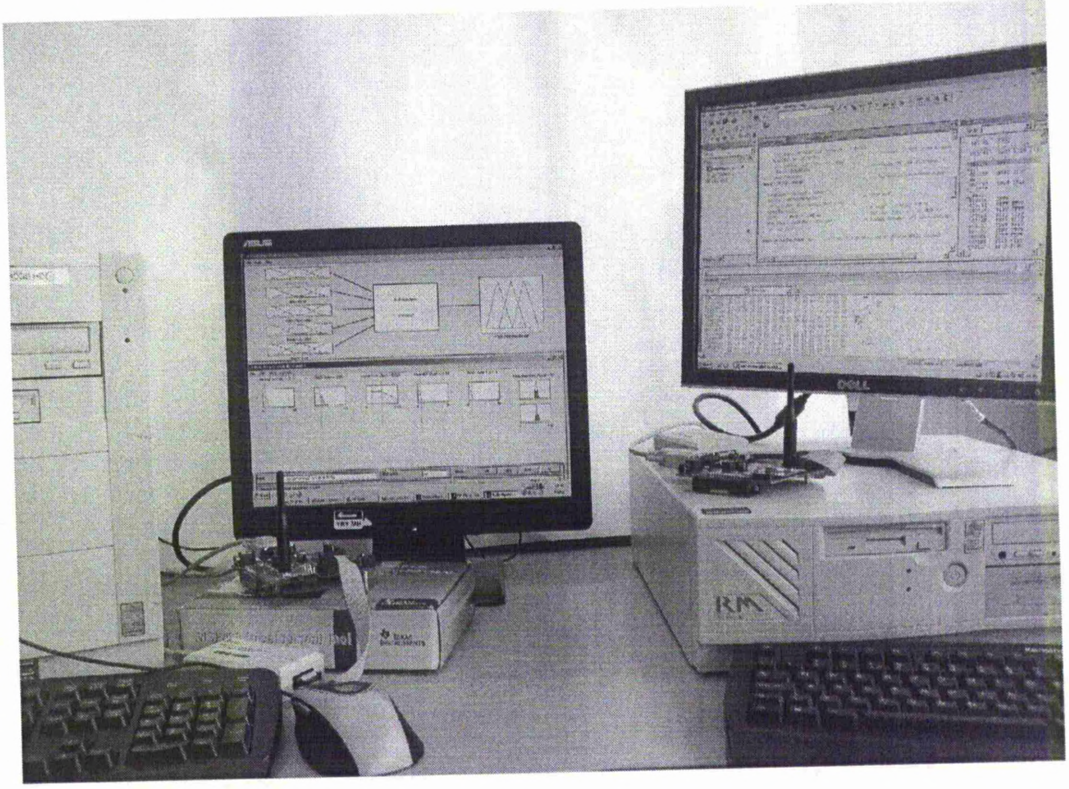



FIGURE 10.8: The shunting system prototype.

- Valve Schedule Updating

  The researcher has proposed a method for auto valve schedule updating in Chapter 9. This method used to calculate the optimum valve schedule parameters, *i.e.* opening and closing durations of the valve. The system would calculate the new valve schedule and update it based on the effect of the fault on the intracranial hydrodynamics or in case of rising ICP for any other reason. The developed shunt prototype has been used to test and evaluate such method and the sequence of this evaluation is as follow,

- The external shunt software located on $PC_2$ is used to derive a new valve schedule based on the patient and implanted system requirements.
- The new schedule was transferred through serial cable into external shunt prototype.
- The wireless shunt protocol was used to wirelessly transfer the new schedule into implanted shunt prototype.
- The new schedule was received by implanted shunting software and then the current schedule replaced by new one based on packet decrypted operation.
- Finally the new schedule was transferred through serial cable into $PC_1$ and then used by the patient model to regulate the valve.

The replacement of valve schedule operation has been done successfully as required by using the developed prototype. The test results validate the proposed method of auto valve schedule updating as well as demonstrates practicality, reliability and flexibility.

- Power Consumption Algorithm

The power consumption algorithm was illustrated in Chapter 3. The prototype of the intelligent shunting system and the power consumption algorithm were implemented and run for 2 hours period. The power consumption algorithm was applied into the system instantaneously. The power consumption was measured using avometer during this period when the system expected in sleeping and active modes based on the system design. The total power required for the system to operate for 2 hours period was calculated before and after applying the power algorithm. The results showed that the measured values matched the proposed algorithm outcome with very high accuracy. As a result of applying such algorithm, the power needed for the system to do its tasks with high efficiency was reduced by more than 93%. The test results demonstrate the reliability and validate the proposed power consumption algorithm.

The outcomes of developing the shunting system prototype are summarised as follow,

- Auto valve schedule updating method was tested, evaluated and validated. The test operation showed that the system derived and calculated valve schedule parameters, autonomously replaced the existing valve schedule by new one, and the valve and ICP sensor followed the new schedule with high system performance.
- Fault detection method was tested, evaluated and validated. This operation showed that various simulated faults were autonomously detected and identified with high accuracy.
- Power consumption algorithm was tested and evaluated. The testing operation showed that the battery life with such protocol can be maximised up to 10 years based on system requirements.
- The prototype was used as an environment to test and evaluate most proposed designs and methods in this study. Such prototype solved the difficulty of evaluating these methods in vivo or in clinical experiments.

- A physical hydrocephalus model was proposed. Such model can be developed in future and used to test, evaluate and validate the mechatronic shunting system.

## 10.5 Conclusion

The final outcomes of developing such prototype are the evaluation of the proposed shunting system overall performance, validation of the proposed methods and system design, testing of different functional aspects under different simulated conditions such as valve blockage, ICP sensor dislocation, valve disconnection and flowmeter fault. In addition, such evaluation leads to greater understanding of the behaviour of the system and of the critical factors affecting the performance. Furthermore, results regarding the energy, frequency and other requirements of the system were reached. In addition, the developed prototype was used to prove the proposed method for interference prevention. Many superfluous packets were sent through the system but they were rejected from the implanted software. To the best of the researcher knowledge, this work is the first to illustrate, test and evaluate a prototype of mechatronic hydrocephalus shunting system.

# Chapter 11

# Conclusions

This work proposes designing and programming an intelligent implantable wireless hydrocephalus shunting system. It is attempted to replace the passive mechanical shunt with a new proposed shunt that improve the potential quality of life for each patient, reduces hospitalisation periods and shunt revisions.

## 11.1 Conclusions

An initial design for the proposed system is illustrated. In addition, four scenarios are simulated to optimise the final design of the proposed system. The final design of the proposed system is presented with features that help in reducing or eliminating the current shunt problems.

The main advantage of the proposed design is the ability of non invasively monitor hydrocephalus patients. A bidirectional wireless protocol is presented, implemented and tested. This protocol presents a communication language between the implantable and external shunting systems. All proposed shunt functions are covered and implemented as a part of such protocol. The system's parts can autonomously communicate, request or response to any request through this communication language.

Various ICP and flow measurements parameters that indicate to the behaviour of ICP signals and flow measurements are extracted and investigated. To optimise the gain of this study, the relations among these parameters with shunt faults and rising/drift ICP were modelled. As an out come of this study, shunt malfunctions parameters were selected to help in early detecting and identify any shunt faults. The revolution of the technology was used in this work to improve the treatment of hydrocephalus patients. An intelligent fuzzy logic technique was used to early detect and identify various current shunt malfunctions. Such method would increase the accuracy, reduce or eliminate the lack of current faults diagnosis methods and reduce the patient suffering.

Mobile health technology and internet are considered in this work by using their facilities to improve the treatment and shunt diagnosis methods. An expert system for analyse patient feedback was proposed and implemented that would play a vital role in treatment and diagnosis of hydrocephalus. The patient who has internet either through his/her mobile or uses browser can feed his/her feeling any time into such expert system and the diagnosis results would appear to him/her with an advice. The physician/consultant has a full access to his/her patients, 24 hours a day and 7 days a week. This would lead to increase the degree of patient care, maximise patient life and eliminate the problem of lack of ICP data.

The monitoring of changes in the patterns and trends of ICP behavior is an important requirement to improve the treatment of hydrocephalus and shunt diagnosis. Intelligent fully automatic self learning methods that produce output based on trends detection were proposed and simulated. Various ICP parameters were derived from simulated hydrocephalus database which was an output of daily monitoring of hydrocephalus and shunting system. In this manner, the trends models of such parameters would yield a generic-form dynamic models that predict the behavior of ICP and given values of these parameters in real (or pseudo-real) time. The outcome of this work were investigation of a self learning database method for historical shunt diagnosis, proposal of trends detection algorithm for ICP parameters, proposal of prediction method for early fault detection and proposal of auto valve schedule updating method. The methods were validated using numerical simulation for hydrocephalus patient with different degrees of valve blockage and leakage.

The fact that intelligent agents are more and more present in the fault detection and isolation area is undeniable. The notion of a self-diagnosis multi-agent system has been presented along with the benefits that are to be gained from this particular approach. In addition, the specific agent architecture along with the internal workings of each agent has been discussed and commented as well as the method of communication between the agents. In the proposed system, negotiations between different presented agents help the system to improve detection and isolation results by giving early warning and efficient decision. The proposed system would use intelligent techniques such as fuzzy logic and expert system to perform the required functions. Real-time shunt components testing and monitoring seem to be the most promising way to decrease the number of shunt revision, then reduce suffering of hydrocephalus patient. The implementation of the proposed multi-agent self diagnosis system will provide a desirable autonomy in terms of self-diagnosing and monitoring the implanted components of the shunting system. The treatment of hydrocephalus would be improved by applying such diagnosing system.

Due to the fact of the sensitivity of clinical assessment as well as the difficulty of evaluation of the proposed system in vivo, a prototype for this system was developed. The final outcomes of developing such prototype were the evaluation of the overall performance of the proposed shunting system, validation of the proposed methods and system design, testing of different functional aspects under different simulated conditions such as valve blockage, ICP sensor dislocation, valve disconnection and flowmeter fault. In addition, such evaluation leads to greater understanding of the behavior of the system and of the critical factors affecting the performance. Furthermore, results regarding the energy, frequency and other requirements of the system were reached. Most of the proposed methods in this study were tested, validated and evaluated by using this prototype.

Finally, it can be concluded that,

- The proposed intelligent shunting system is seen as the future in hydrocephalus treatment, potentially significantly reducing hospitalisation periods and shunt revisions.
- A novel method was proposed and developed to utilise the implanted battery capacity that would increase the battery life to supply the needed power to the implanted shunt component as long as possible.
- A management protocol was proposed which is considered the way of solving most of the current shunt problems, personalising treatment and real time monitoring of shunt performance.
- The proposed shunting system gives hydrocephalus patients the freedom to go anywhere they like while receiving medical services and healthcare in a timely fashion.
- The proposed shunt with self learning method would cooperate to improve the treatment of hydrocephalus.
- Even though the shunt components are implanted inside the human body, it is possible to detect any malfunctions within very short time.

- New programmable shunt valves with shunt management and self-diagnosis system hold promise for reducing the need for shunt revision surgery. By using the proposed system, the patient can take part in managing the symptoms and diagnosing the shunt.

- Valuable information about hydrocephalus and shunt diagnosis would be available for future learning to improve treatment and management of hydrocephalus

- A final point: to the best of the author knowledge, no formal studies have been done based on wireless reprograming implanted shunting system, self diagnosing of implanted components, reducing the power needed for implanted components and self learning from ICP data.

## 11.2 Future Prospects and Limitations

Future enhancements should incorporate more input parameters *i.e.* patient daily activities (sleeping and working times, type of work (sitting, standing)) and other parameters derived from ICP traces, in developing and implementing the patient expert system. Furthermore, such system should be clinically evaluated by comparing the outcome of this system with the physician diagnosis for samples of patient.

Future enhancements should be taken to improve the shunt self diagnosis system by applying neural network technique and simulate different types of patients *i.e.* infant patient, toddlers patient, adult patient. In this case, a neural network technique would be used to cluster and identify various shunt faults based on malfunctions parameters. In addition, the interfacing between such system and the proposed shunting system can be prototyped to evaluate the whole shunting system.

Future enhancements should be taken to finsihe the development of self-diagnosis multi-agent system using AgentSpeak (Jason). A physical model of the intracranial hydrodynamics presented in Chapter 10 can be developed and used as a dynamic environment for testing and evaluating the proposed methods, algorithms and the intelligent shunting system.

The obstacles facing this research can be categorised into three categories; technical issues (such as ICP sensor inaccuracy or breakage, power limitation, implantable memory size limitation, product size limitation, mechatronic valve intermittent problems), clinical issues (such as difficulty of clinical evaluation, lack of real ICP data), and miscellaneous issues (such as physician and patient mentality, lack of previous research in this area). Nevertheless, future advancements have promising solutions for such problems.

# Appendix A

# System Design

## A.1 The Valve - Microcontroller Subsystem

The main functions of this subsystem (shown in Figure A.1) are to control the opening /closing of the valve and to save the valve state. The input, output and other details of this subsystem are illustrated below

- Function: open/cloe the valve.
- Description: microcontroller should send a signal to the valve, this signal should be triggered by the internal valve schedule.
- Input: signal from external station ($I_0$), signal from agent software ($I_1$), signal from pressure sensor ($I_2$).
- Output: signal to the valve switch.
- Source: internal program.
- Destination: the valve.
- Communication method: the microcontroller is triggered by the internal program which should be saved in the flash memory, a signal is transferred

to the output port, the signal value is converted from digital to analogue by using A/D converter, the analogue signal pens/closes the valve. Time counter starts to calculate the open/close valve duration time and save it in the flash memory.

- Communication: microcontroller-valve communication, microcontroller flash memory communication.
- Action: input data to the microcontroller input port, and then the data is transferred to the microprocessor, the internal program is scaned output result should be is send to the valve.

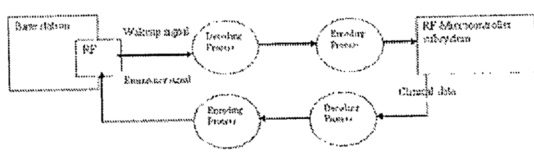



FIGURE A.1: Valve - microcontroller subsystem.

## A.2 Intelligent Software Subsystem

The main function of the software subsystem (shown in Figure A.2) is to autonomously modify the internal program in away that personalise the management of hydrocephalus for this particular patient thus controlling the open/close valve operation.

- Function: update internal schedule, control opening/closing of the valve based on sensory inputs (ICP, flow, patient feedback).
- Description: the intelligent programme should receive the user's feedback, analyse it and make a suitable decision based on this feedback such as sending

a signal to the valve, saving the feedback in flash memory, reading from memory, collecting data or no change.

- Input: signal from external station ($I_0$), signal from itself ($I_1$), signal from pressure sensor ($I_2$).
- Output: signal to the microcontroller.
- Source: user's feedback, intelligent software.
- Destination: microcontroller.
- Communication method: the microcontroller executes the intelligent software program that is saved on the flash memory (internal program responsible for upload the intelligent program from flash memory and execute it). The action should be taken depend on the programme output result, the signal transfer to the output port (the signal value should be converted from digital to analogue by using D/A converter, the analogue signal through away to the valve. Time counter starts to calculate the open valve duration time.
- Communication: intelligent software - microcontroller communication, intelligent software - user communication.
- Action: Intelligent software receives the user's feedback and analyse it, make an interrupt to request an execution process, upload the intelligent program to the RAM and execute it, take an action or actions e.g. send a signal to the valve, save the feedback in the patient's library, read from memory or no change).

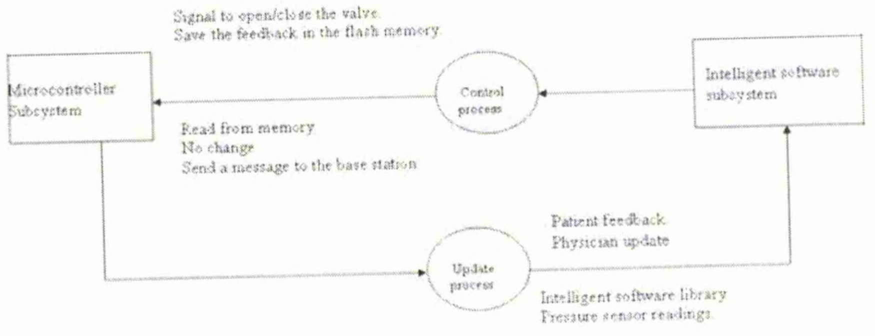



FIGURE A.2: Intelligent software subsystem

## A.3 The Memory - Microcontroller Subsystem

The main responsibility of this subsystem (shown in Figure A.3) is to mange the memory access method.

- Function: save the internal program, save the intelligent software, save patient's library.
- Description: the internal program (operating system) and the intelligent software are saved in the flash memory at different locations. The internal program is loaded to the RAM and executed by the microprocessor, while the patient's feedback is received by the microcontroller and transferred to be saved in the patient's library. The intelligent software and external user have full permission to access (read/write) the patient's library.
- Input: data from the microcontroller ($I_0$), data from patient's library ($I_1$), data from base station ($I_2$), and valve status ($I_3$).
- Output: data to the microcontroller ($O_0$), data to base station ($O_1$).
- Source: user's feedback, intelligent software, operating system.
- Destination: microcontroller.

- Communication method: the microprocessor uploads the operating system from flash memory to the RAM and executes it, the microprocessor uploads the intelligent software program to the RAM which should be saved in the flash memory and execute it. The valve status should be saved in the patient's library. The microprocessor save the results in the flash memory, the users can be read or write from/to the flash memory when he/she need it. The communication operation should be doing by using data, control and address buses.
- Communication: memory system - microcontroller communication, memory system - valve communication, memory system- users' communication.
- Action: microprocessor uploads the operating system and intelligent software, then execute them, save the result in the flash memory.

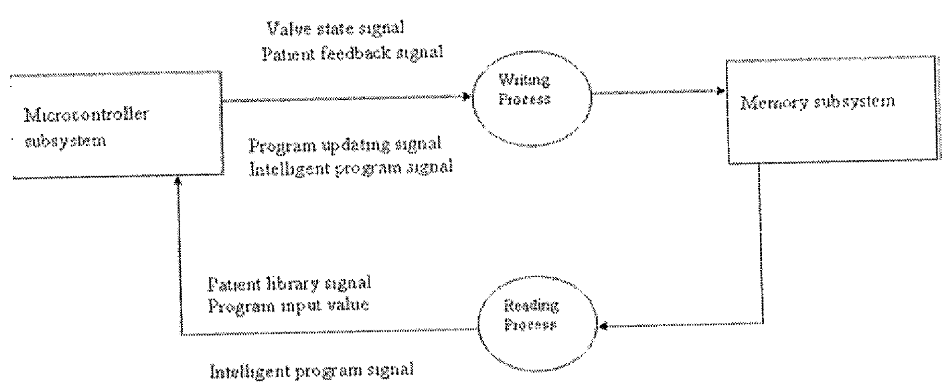



FIGURE A.3: Base Station Module (BSM).

## A.4 RF-Microcontroller Subsystem

The main function of this subsystem (shown in Figure A.4) is to manage the sending/receiving data operation between base station and implantable system.

In addition, it is used to receive a wake up signal or any update from the base station.

- Function: receive a wake up signal, receive emergency signal, receive any update and send a data from implantable system to the base station.
- Description: the base station sends a wakeup signal to change the implantable system state, or an emergency signal to the implantable system. Also the base station can request any data from implantable system.
- Input: wakeup signal from the base station ($I_0$), emergency signal from the base station ($I_1$)), any other request ($I_2$).
- Output: clinical data from the library ($O_0$).
- Source: base station.
- Destination: the valve, the memory system.
- Communication method: the base station sends the signals through the RF transceiver to the implantable system. The analogue data would be decoded before it is send. On the other hand, the implantable system would send a clinical data to the base station.Microcontroller executes the internal program which should be saved in the flash memory, the programme output transfer to the output port, the signal value convert from digital to analogy by using A/D converter, the analogy signal through away the valve. Time counter starts to calculate the open valve duration time and save it in the flash memory.
- Communication: base station-RF microcontroller communication.

- Action: the signals will be sending from base station by using RF depend on the communication protocol and encode/decode method that will be selected. Input data to the microcontroller input port, and then the data transfer to the microprocessor. The data will be sending from the implantable system to the base station by using RF transceiver.

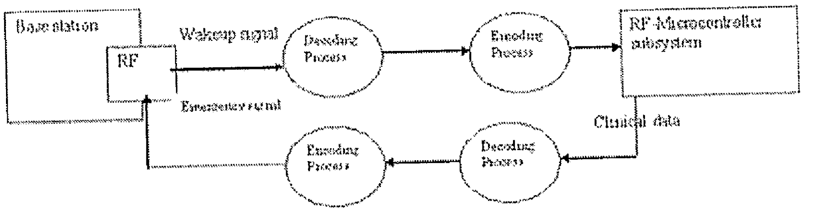



FIGURE A.4: Base station-RF-Microcontroller subsystem

# Appendix B

# Designing of Wireless shunting protocol

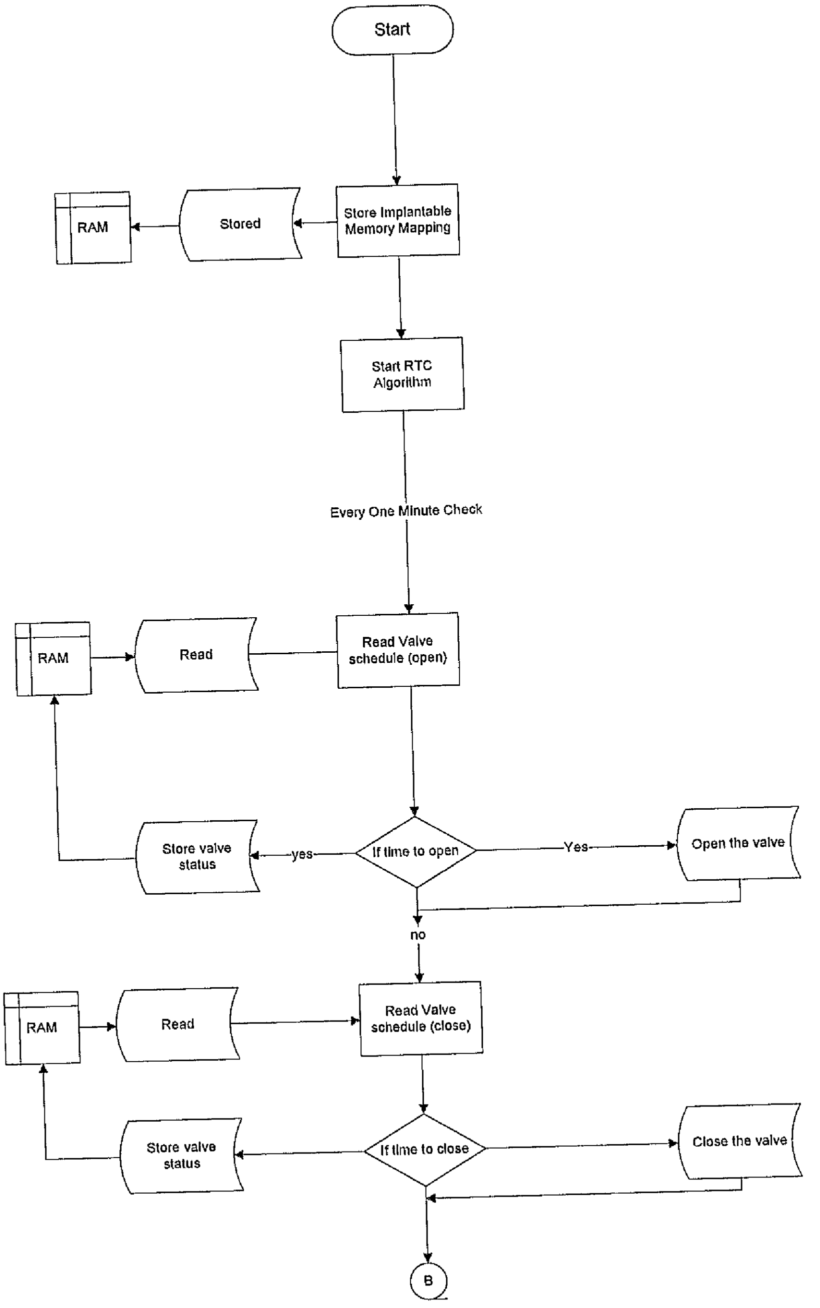



FIGURE B.1: A flow chart of implanted shunting software design (first part).

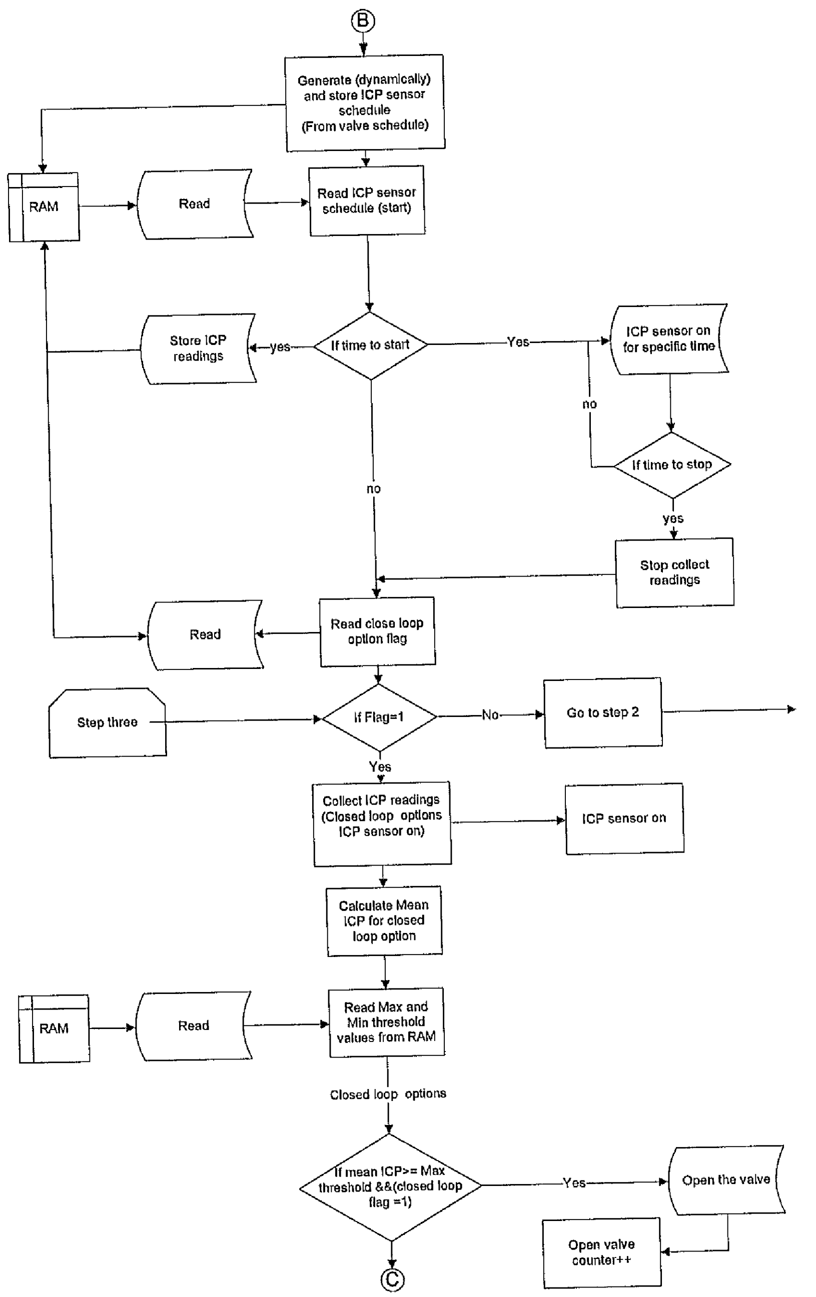



FIGURE B.2: A flow chart of implanted shunting software design (second part).

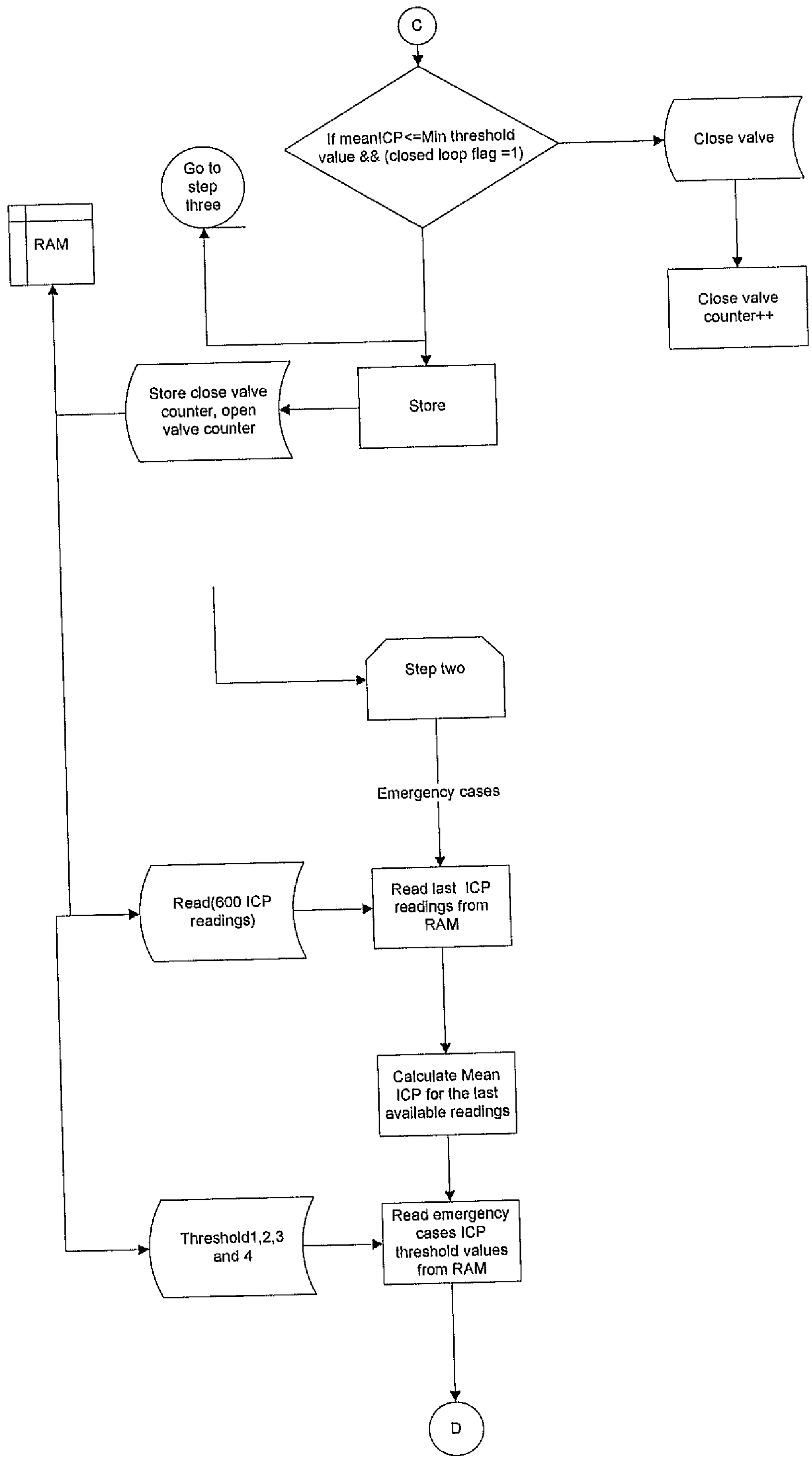



FIGURE B.3: A flow chart of implanted shunting software design (third part).

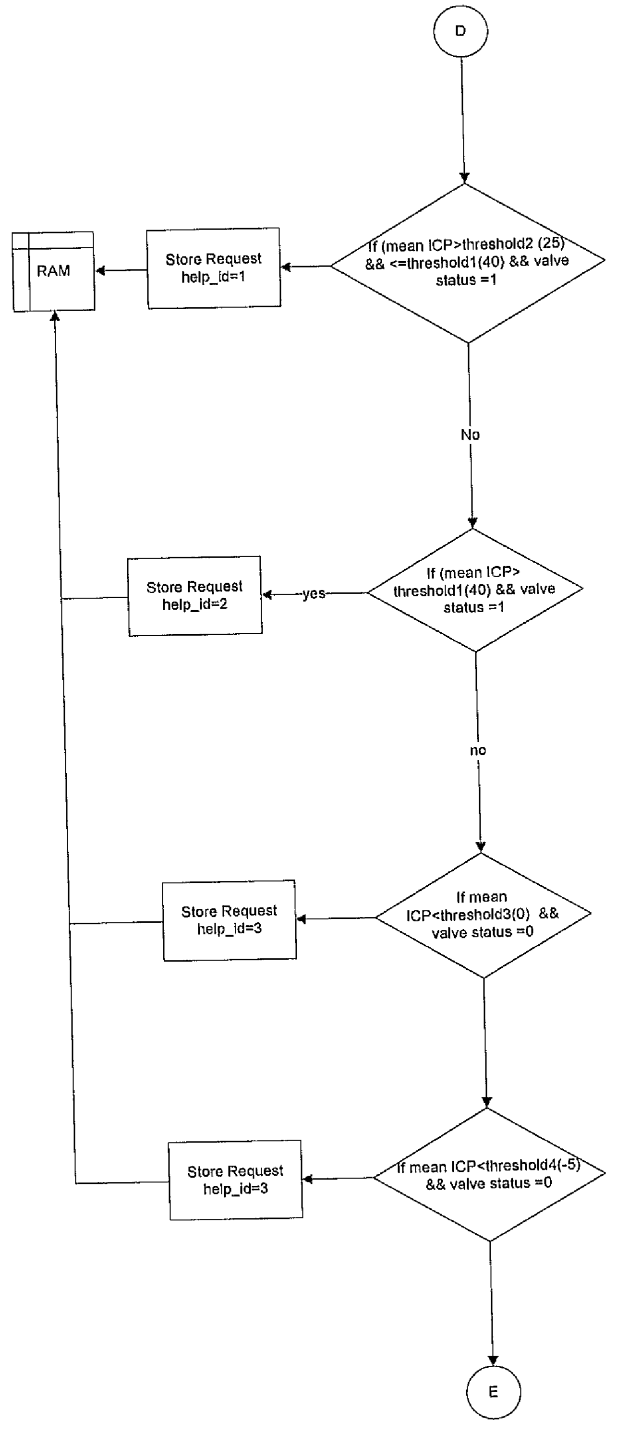



FIGURE B.4: A flow chart of implanted shunting software design (fourth part).

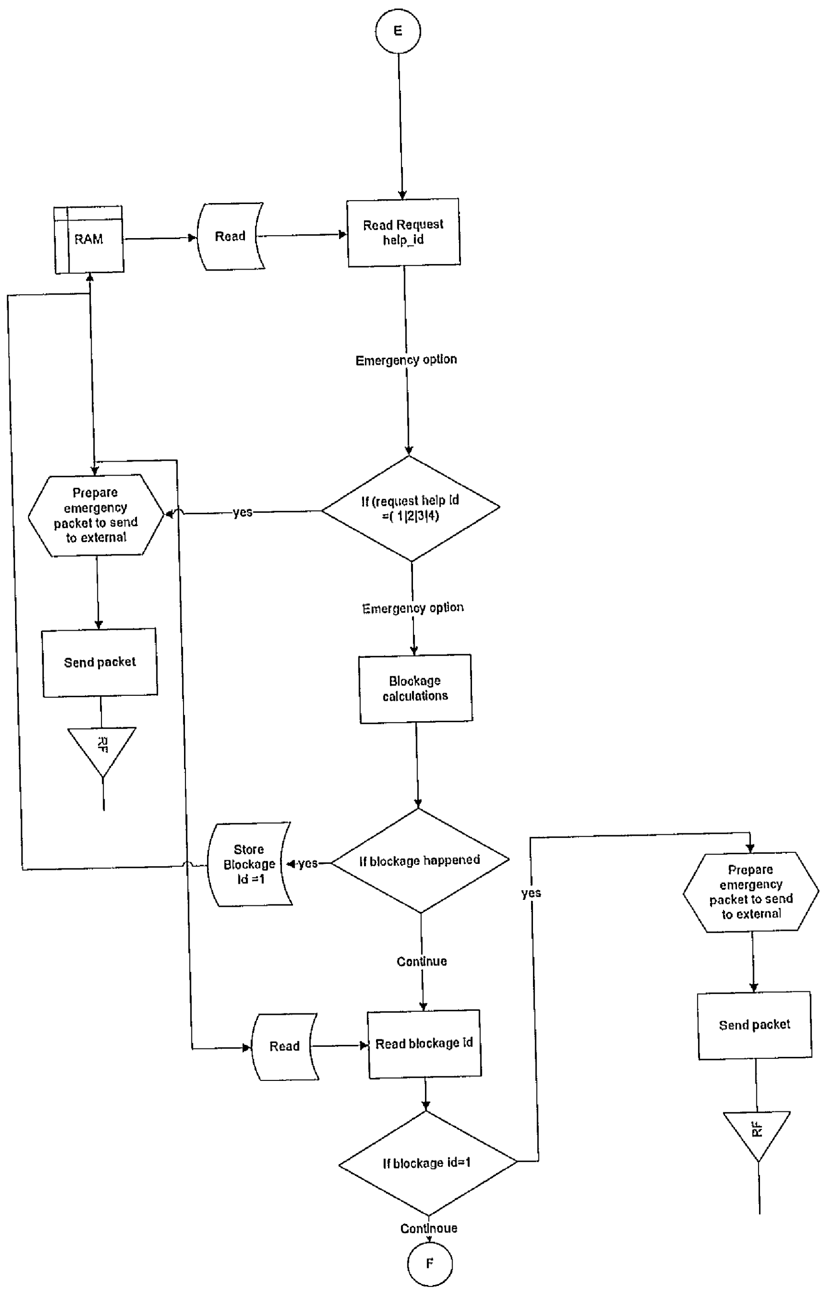



FIGURE B.5: A flow chart of implanted shunting software design (fifth part).

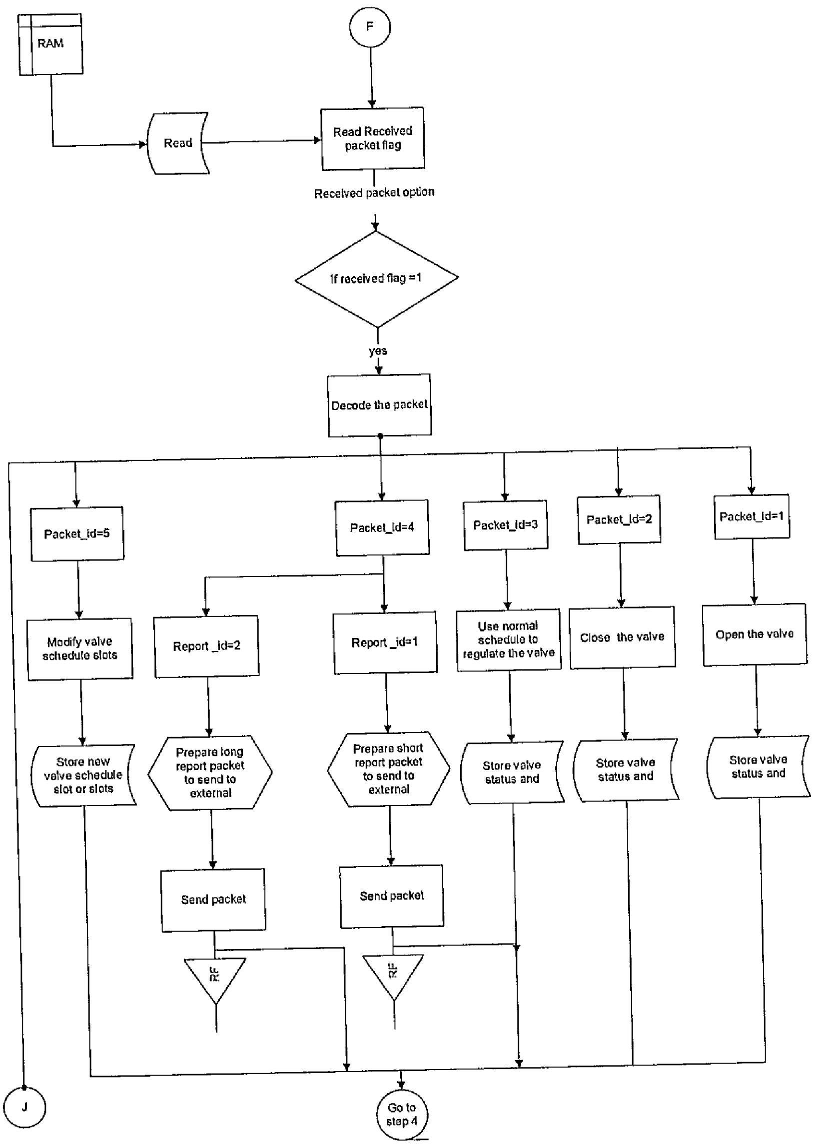



FIGURE B.6: A flow chart of implanted shunting software design (sixth part).

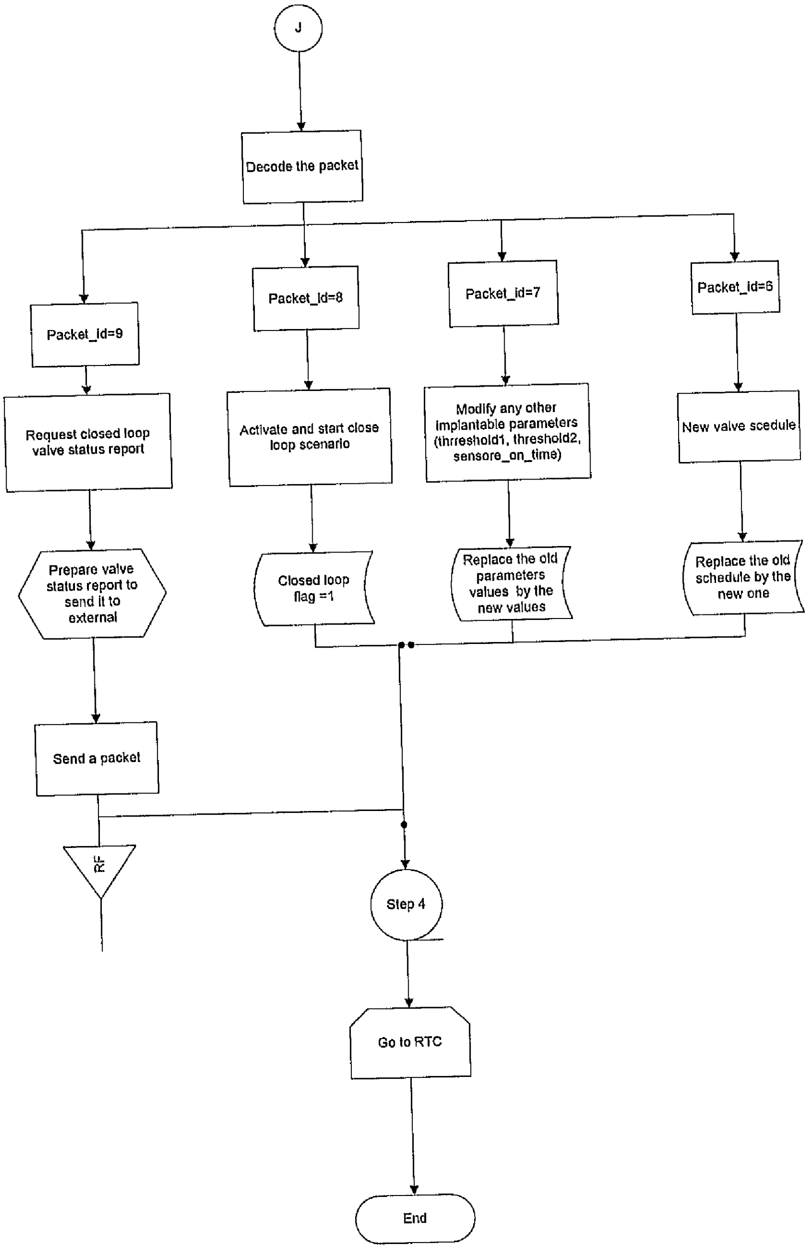



FIGURE B.7: A flow chart of implanted shunting software design (seventh part).

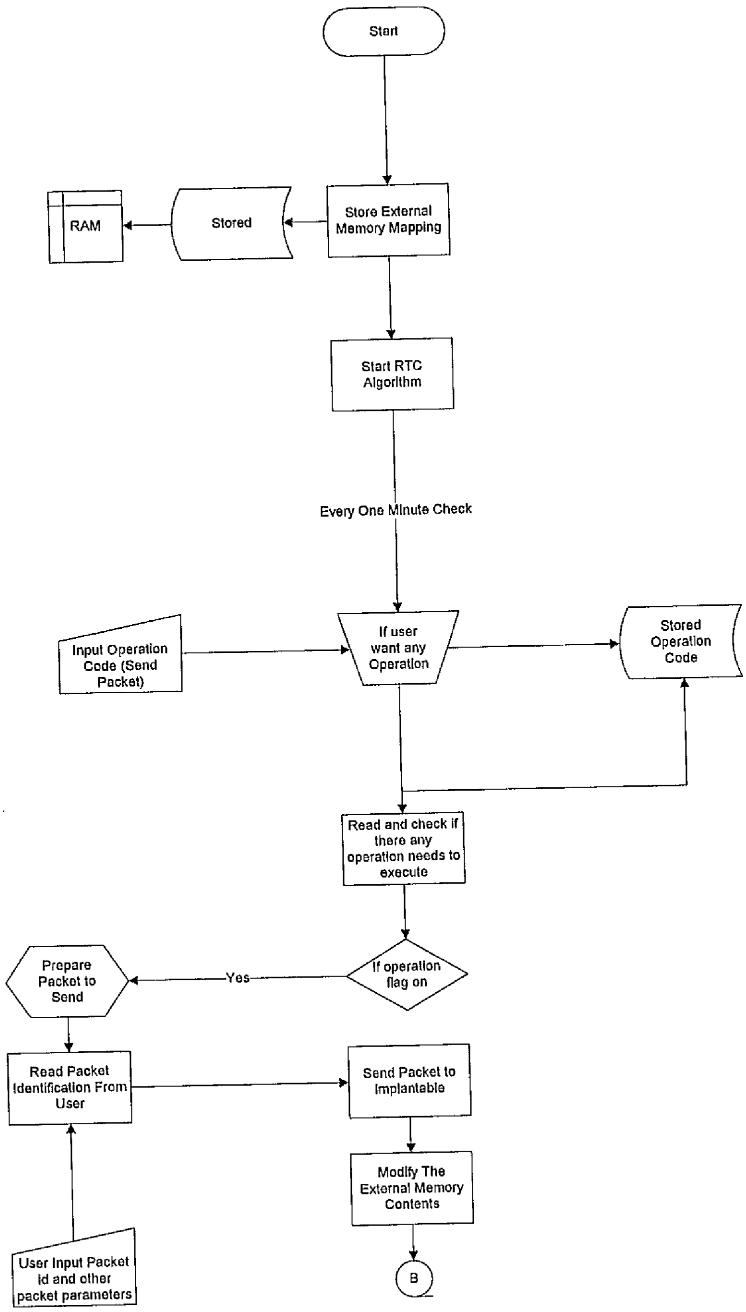



FIGURE B.8: A flow chart of external shunting software design (first part).

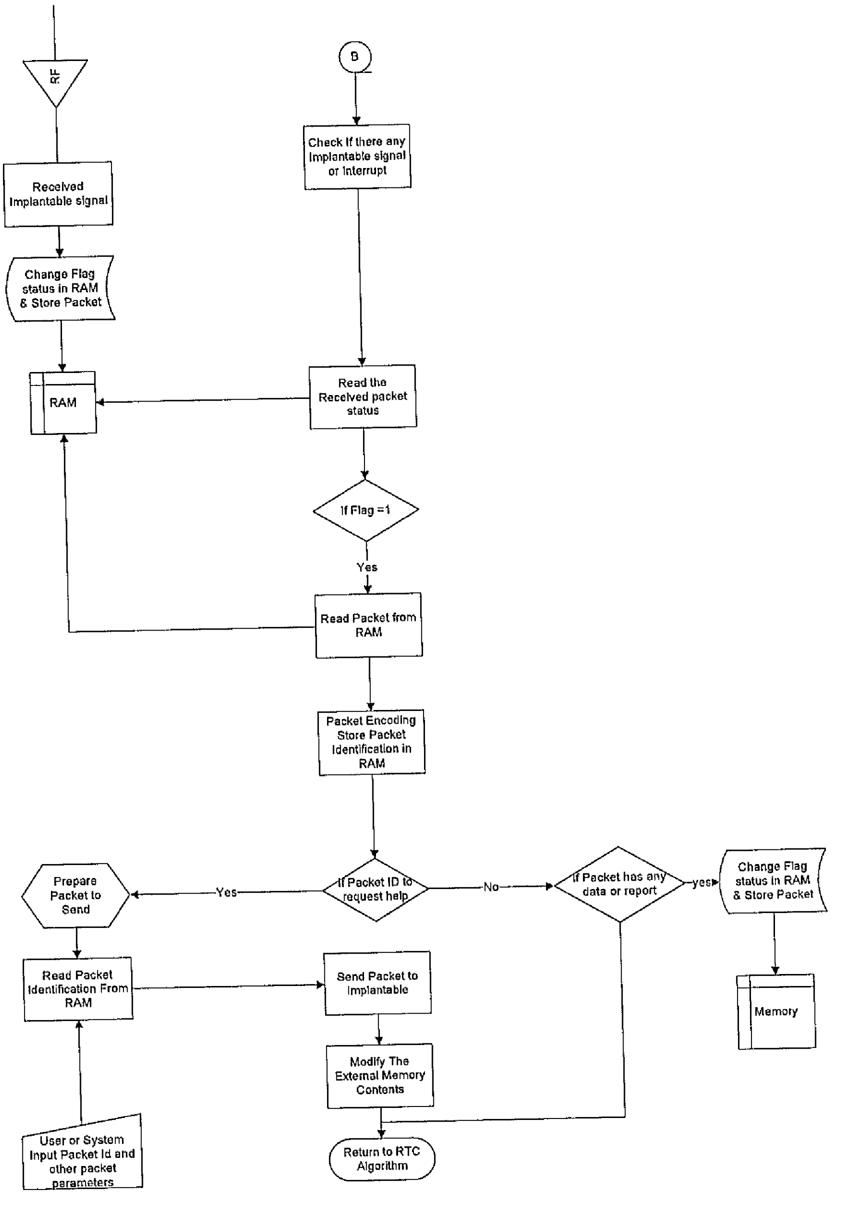



FIGURE B.9: A flow chart of external shunting software design (second part).

# Appendix C

# The code of Serial Interface operation between PC and microcontroller

## C.1 Microcontroller Code

### C.1.1 Send Data from Microcontroller to Matlab

```
//*****************************************************************************

This code was written using C language. MSP430FG4618 Development Tool and the MSP430FG4618
device were used. The USCI module in Ultra-Low Pwr UART 9600 connected to a PC's Simulink.
When the connection is established, the data read from RAM and send through RS-232 interface to
the Simulink.

Instructions:

  • This program requires to configure the USCI module in UART mode:
      ✓ Configure USCI control registers
      ✓ Configure baud rate generatiob
      ✓ Configure ports
      ✓ Enable RX interrupts
      ✓ Configure FLL+ at 8 MHz

This code is Copyrighted to Abdel Rahman Alkharabsheh, April 2010, Built with IAR Embedded
Workbench Version: 4.21

//*****************************************************************************

#include "msp430xG46x.h"

#define CSAVE ((char *) 0x1120)

void sendbuffer(int n);

char *psave; // global pointer to save

char nsave; // input counter

void UARTSetup(void) // Initialize UART device at USCI unit

{

 //1) intialization / re-configuration process <- BGIN

 UCA0CTL1 |= UCSWRST; // Set UCSWRST -- needed for re-configuration process

 // 2) -> intialize all USCI registers Set <-Begin

 UCA0CTL0 =0x00;          //UCA0CTL0 -> CONTROL REGISTER 0

 UCA0CTL1 =0x81;          //UCA0CTL1 -> CONTROL REGISTER 1

 UCA0BR0 = 0x34;            // 9600 from 8MHz -> SMCLK

 UCA0BR1 = 0x00;            //

 UCA0MCTL = 0x11;            // UCA0MCTL Modulation control register

  //3) Configure pots
```

Figure C.1: A microcontroller code to send ICP data from RAM to matlab (first part).

### C.1.2 Send Data from Simulink to microcontroller

```
P2SEL |= 0x30;                 // P2.4,P2.5 = USCI_A0 TXD/RXD
//4) Clear UCSWRST via software <- Begin
UCA0CTL1 &= ~UCSWRST;          // **Initialize USCI state machine**
//5) Enable interrupts <- Begin
IE2 |= UCA0RXIE;               // Enable USCI_A0 RX interrupt
} // end function
void CLKInit(void)             // Initialize the system clock
{
/* disable watchdog timer */
WDTCTL = WDTPW+WDTHOLD;        // Stop WDT
// Configure microcontroller clock
SCFQCTL = 121;                 /* N =121*/ // (FIND OUT N)
SCFI0  = FLLD_2 | FN_4;        /* Set D=2, range 1.3-12.1MHz */
FLL_CTL0 = DCOPLUS | XCAP14PF; /* Enable divider, set osc capacitance = ~8pF */
} // end function
void writechar(char ch)        // write a single char at RS-232 USCII channel
{
while(!(IFG2&UCA0TXIFG));      // USART1 TX BUFFER READY?
UCA0TXBUF = ch;                // Output character
}// end function
void main(void)
{
// initialize system clock
CLKInit();
// initialize communication interface
UARTSetup();
// Allow interrupts
```

FIGURE C.2: A microcontroller code to send ICP data from RAM to matlab (second part).

## C.2 Matlab Code

```
_BIS_SR(GIE);           // interrupts enabled
char save[100];          // Address to store Matlab output via RS-232
// psave=save;
nsave=0;
psave=CSAVE;
sendbuffer(8);
#pragma vector=USCIAB0RX_VECTOR
__interrupt void USCI_UART_0_RX_RSI(void)
{
 *(psave++)=UCA0RXBUF;           //  Store recieved data in RAM
 ++nsave;
}
void sendbuffer(int n) // send n characters of the buffer
{
 int i=0; // loop index pointer variable (reuseable)
 while(i<n)
   writechar(*(CSAVE+(i++)));
}
```

FIGURE C.3: A microcontroller code to send ICP data from RAM to matlab (third part).

```
//*****************************************************************************
When the connection is established, the output of the Simulink sent to t the microcontroller's RAM
through thr RS-232 interface.
#include "msp430xG46x.h"
char *psave; // global variable to save
void UARTSetup(void) // initialize UART device at USCI unit
{
 //1) intialization / re-configuration process <- BGIN
  UCA0CTL1 |= UCSWRST; // Set UCSWRST -- needed for re-configuration process
  // 2) -> intialize all USCI registers Set <-Begin
  UCA0CTL0 =0x00;          //UCA0CTL0 -> CONTROL REGISTER 0
  UCA0CTL1 =0x81;          //UCA0CTL1 -> CONTROL REGISTER 1
  UCA0BR0 = 0x34;           // 9600 from 8MHz -> SMCLK
  UCA0BR1 = 0x00;           //
  UCA0MCTL = 0x11;           // UCA0MCTL Modulation control register
    //3) Configure pots <- Begin
   P2SEL |= 0x30;          // P2.4,P2.5 = USCI_A0 TXD/RXD
   //4) Clear UCSWRST via software <- Begin
   UCA0CTL1 &= ~UCSWRST;          // **Initialize USCI state machine**
   //5) Enable Interrupts <- Begin
    IE2 |= UCA0RXIE;          // Enable USCI_A0 RX Interrupt
 } // end function
 void CLKInit(void)          // Initialize the system clock
 {
   /* disable watchdog timer */
   WDTCTL = WDTPW+WDTHOLD;          // Stop WDT
   // Configure microcontroller clock
   SCFQCTL = 121;          /* N =121*/ // (FIND OUT N)
```

FIGURE C.4: A microcontroller code to receive ICP data from hydrocephalus model(first part).

```
SCFI0  = FLLD_2 | FN_4;              /* Set D=2, range 1.3-12.1MHz */
FLL_CTL0 = DCOPLUS | XCAP14PF;       /* Enable divider, set osc capacitance = ~8pF */
} // end function
void writechar(char ch)     // write a single char at RS-232 USCII channel
{
while(!(IFG2&UCA0TXIFG));            // USART1 TX BUFFER READY?
 UCA0TXBUF = ch;                     // Output character
}// end function
void main(void)
{
 // initialize system clock
 CLKInit();
 // initialize communication interface
 UARTSetup();
 // Allow interrupts

 _BIS_SR(GIE);              // Interrupts enabled
 char save[100];            // Address to store Matlab output via RS-232
// psave=save;
 psave=(char *) 0x1120;
 while(1) {}        // No return from here
} // end main
#pragma vector=USCIAB0RX_VECTOR
__interrupt void USCI_UART_0_RX_RSI(void)
{
 *(psave++)=UCA0RXBUF;              //  Store recieved data in RAM
}
```

FIGURE C.5: A microcontroller code to receive ICP data from hydrocephalus model(second part).

```
% When the connection is established, the output of the Simulink sent to t the
% microcontroller's RAM through thr RS-232 interface and the output of
microcontroller send back to Simulink.

% Send to microcontroller
%-----------------------------------------------------------------

s = serial('COM1');

set(s,'Timeout',100); % was 100

fopen(s);

ICP=[127 126 125 124 123 122 121 122 0 123 124 125
126 127 10 20 30 40 50 60 70 8 9 10 11 12 5];

fwrite(s,ICP);

fclose(s);



% ---------------------------------------------------------------

 %  Received from microcontroller


 s = serial('COM1');

set(s,'Timeout',100); % was 100


 fopen(s);

[control,count]= fread(s,8,'int8');

fclose(s);
```

FIGURE C.6: A Matlab code to send/receive ICP data to/from microcontroller.

# Appendix D

# Graphical User Interface for Simulation of Shunt Malfunctions

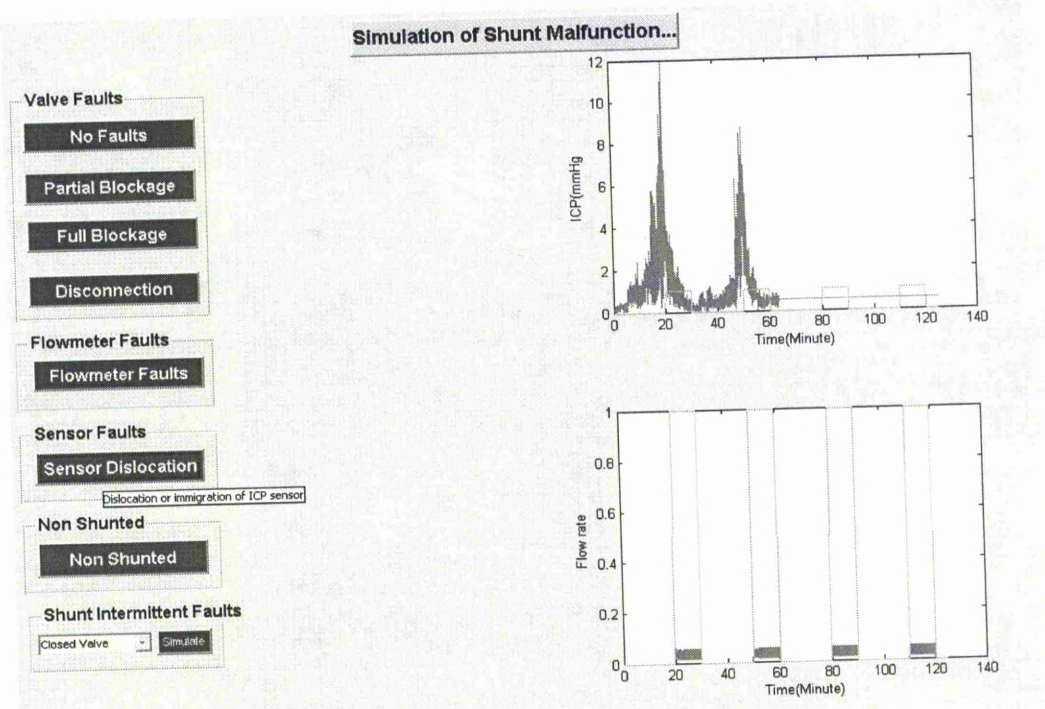



FIGURE D.1: ICP sensor Dislocation

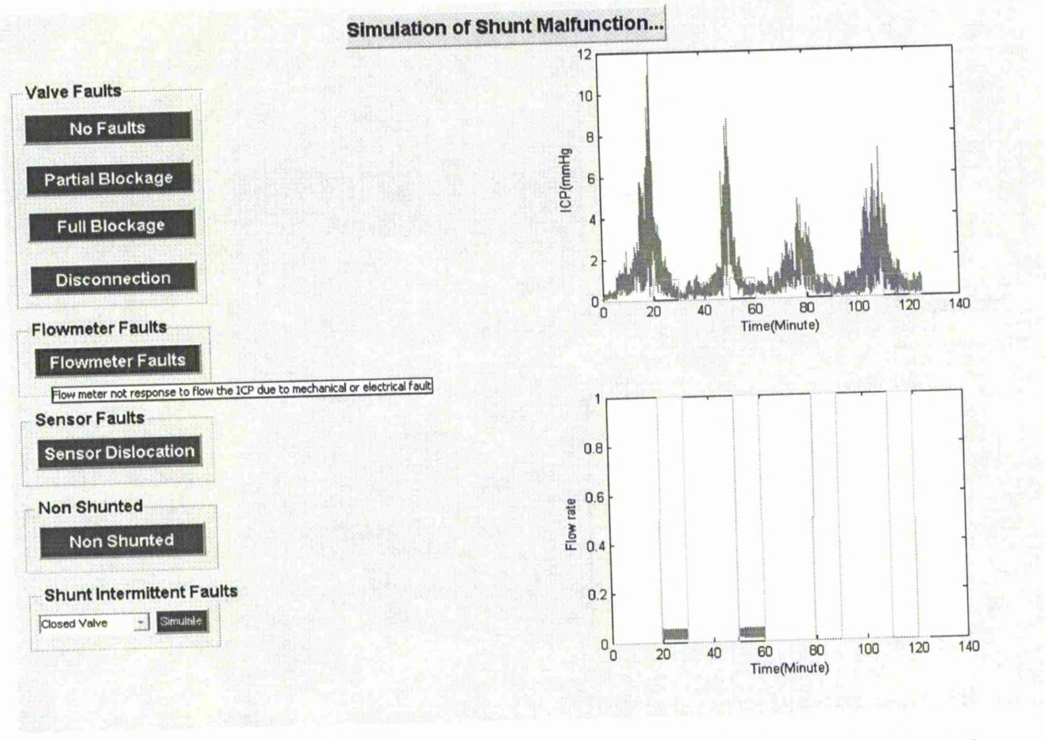



FIGURE D.2: Flowmeter fault ( flowmeter not response due to mechanical or electrical fault.

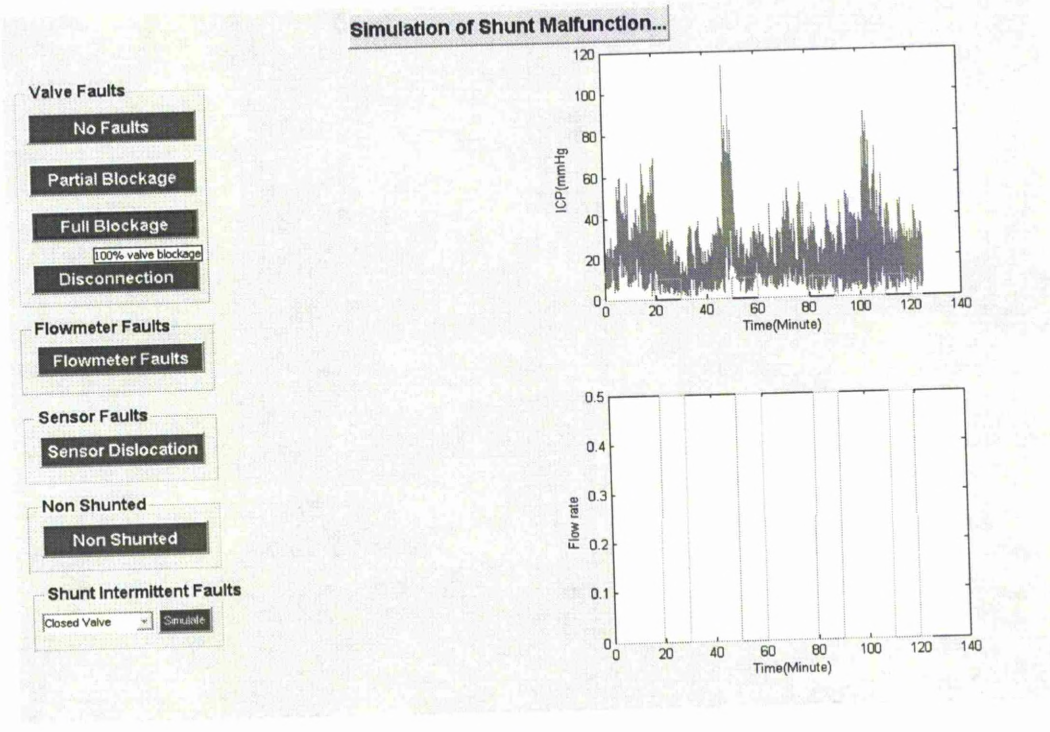



FIGURE D.3: Full valve blockage.

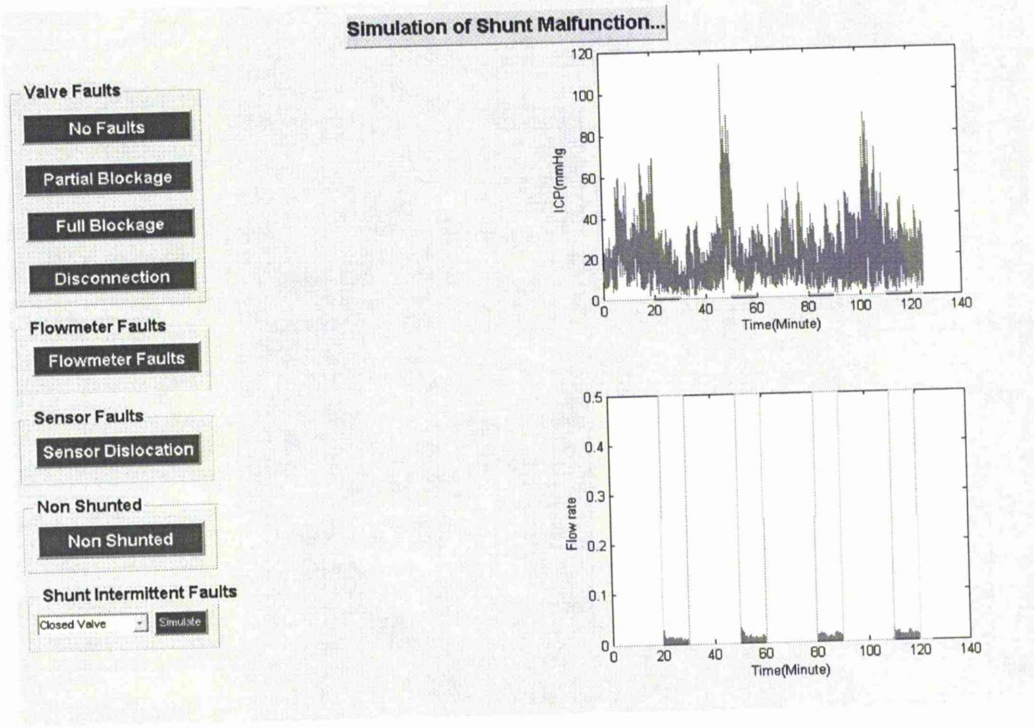



FIGURE D.4: Partial valve blockage

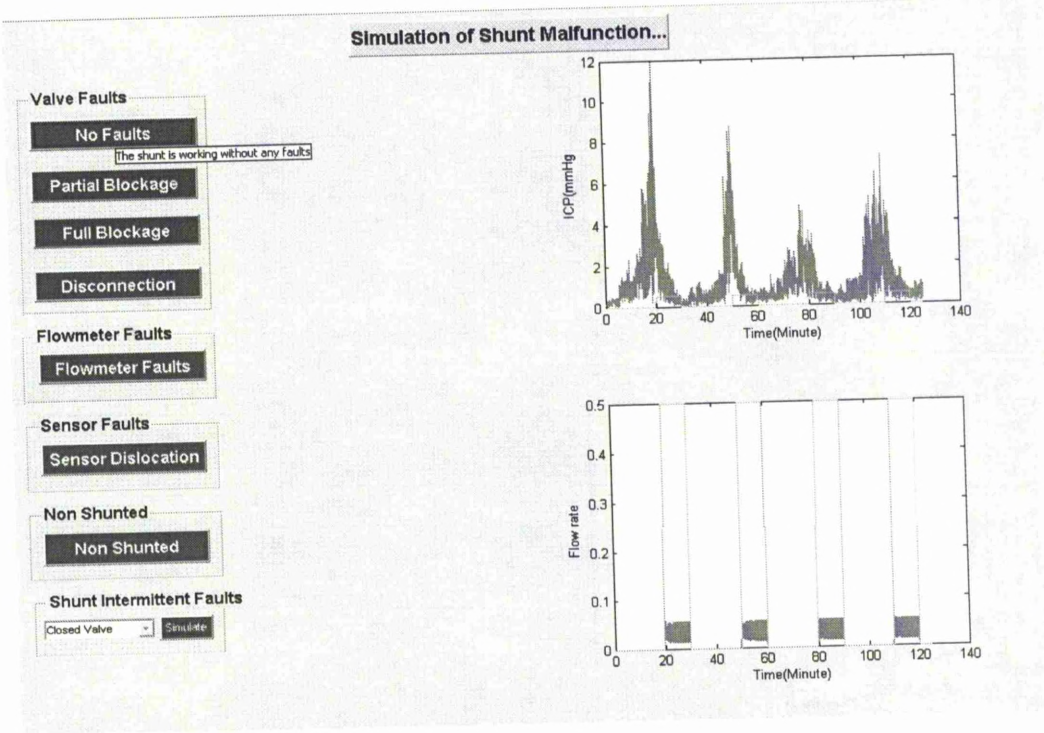



FIGURE D.5: No fault

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